Jeffrey A. Bowersox, OSB # 81442
Email: Jeffrey@bowersoxlaw.com
Bowersox Law Firm, P.C.
5285 Meadows Rd, Ste. 320
Lake Oswego, OR 97035
Tel: (503) 452-5858
Fax: (503) 345-6893

Stuart L. Goldenberg *To Be Admitted Pro Hac Vice*
Marlene J. Goldenberg *To Be Admitted Pro Hac Vice*
800 LaSalle Avenue, Suite 2150
Minneapolis, MN 55402
Email: slgoldenberg@goldenberglaw.com
Email: mjgoldenberg@goldenberglaw.com
Tel: (612) 333-4662
Fax: (612) 367-8107

Turner W. Branch, *To Be Admitted Pro Hac Vice*
Margaret M. Branch, *To Be Admitted Pro Hac Vice*
Adam Funk, *To Be Admitted Pro Hac Vice*
Email: tbranch@branchlawfirm.com
Email: mbranch@branchlawfirm.com
Email: afunk@branchlawfirm.com
The Branch Law Firm
808 Travis St., Suite 1553
Houston, TX 77002
Fairfax, VA 22030
Tel: (713) 224-1500
Fax: (713) 224-1622

Of Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF OREGON

PORTLAND DIVISION

ROBERT SKOUBO, and DIANE SKOUBO, Plaintiffs, v.	Case No. 2:14-cv-461 **COMPLAINT FOR DAMAGES** **DEMAND FOR JURY TRIAL** (1) Fraudulent Misrepresentation and Fraud in the Inducement (2) Strict Products Liability— Failure to Warn (3) Strict Products Liability— Design

MEDTRONIC, INC., and MEDTRONIC SOFAMOR DANEK USA, INC., Defendants		Defect (4) Strict Products Liability—Misrepresentation (5) Products Liability- Negligence (6) Breach of Express Warranty (7) Breach of Oregon's Consumer Protection Statutes (8) Loss of Consortium (9) Punitive Damages

INTRODUCTION

1. This case involves a spinal surgery in which a bio-engineered bone graft device known as the Infuse® Bone Graft ("Infuse®") was implanted in Plaintiff in an off-label manner.

2. Infuse® is a bio-engineered liquid bone graft product classified by the FDA as a medical device. It was developed, designed, manufactured, marketed, and distributed by a division of Medtronic, Inc. known as Medtronic Sofamor Danek USA, Inc. (collectively "MEDTRONIC" or "MEDTRONIC Defendants"). Infuse® is used in spinal fusion surgeries, and its purpose is to foster fusion between the vertebrae without implanting a patient's own bone or cadaver bone between the vertebrae in the spine, as the latter two options require a surgeon to harvest bone from the patient's own hip or risk the rejecting of cadaver bone.

3. This case involves a spinal fusion surgery in which Infuse® was used in an *off-label* manner (i.e., in a way that was not approved by the FDA). Infuse® is approved by the FDA and is indicated *only*: (1) for anterior lumbar interbody fusions; (2) some tibia fractures; and (3) some specific dental surgeries not relevant to this case. This case concerns an off-label use in a lumbar fusion procedure. Infuse® is only approved by the FDA for lumbar surgery that is performed through the abdomen (anterior approach) when it is used *in combination with* an LT-Cage™, a hollow metal cylinder that is meant to hold the active ingredient in Infuse®, rhBMP-2 protein.

4. Infuse is *not* approved by the FDA for use in cervical spine surgery, or for any lumbar surgery performed through the back or side of the body (transforaminal, posterior or posterolateral approaches). All cervical spine surgeries, many lumbar surgeries (where the approach is not through the abdomen), and all Infuse® back surgeries that are not done with an LT-Cage™ are considered off-label uses.
5. Despite this lack of FDA approval and the FDA's explicit concerns about the dangers to patients posed by off-label uses, Infuse® was improperly promoted by MEDTRONIC to be used off-label for transforaminal, posterolateral, and posterior approach spine fusions, cervical spine fusions, and procedures without the LT-Cage™.
6. Patients' spine surgeons, including Plaintiff's surgeon, were persuaded by MEDTRONIC and by MEDTRONIC's consultant "Key Opinion Leaders," who were paid physician promoters, to expand their use of Infuse® for off-label uses such as transforaminal approach lumbar fusions.
7. When Infuse® is used off-label, it can cause severe injuries to the patient, including Infuse®-induced bone overgrowth and other complications that often necessitate risky, painful, and costly revision surgeries, which may not cure the problems caused by Infuse®.
8. This uncontrolled bone growth (also known as "ectopic," "heterotopic," or "exuberant" bone growth) can result in severe damage to or compression of the surrounding neurologic structures in the spine, and bone can grow onto or around the spinal cord or nerve roots. When nerves are compressed by excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and a need for additional surgery.
9. When Infuse® is used off-label, it can also cause or contribute to other serious injuries and complications, including extreme inflammatory reactions, chronic radiculitis, retrograde

ejaculation, sterility, osteolysis (bone resorption), displacement or migration of the spacer cage, pseudoarthrosis, and worse overall outcomes.

10. Notwithstanding overwhelming and substantial evidence (including MEDTRONIC-sponsored studies) demonstrating these increased risks of adverse reactions from off-label use of Infuse®, MEDTRONIC recklessly and/or intentionally misrepresented, minimized, downplayed, disregarded, and/or completely omitted these off-label risks while promoting Infuse® to spine surgeons for off-label uses. In fact, MEDTRONIC promoted to spine surgeons and patients the use of the product in dangerous off-label procedures, thereby demonstrating a conscious disregard for the health and safety of spinal fusion patients like the Plaintiff.

11. Moreover, the actual rate of incidence of serious side effects from off-label use of Infuse® is, in fact, much greater than that disclosed by MEDTRONIC to spine surgeons and patients. With respect to the off-label approaches, MEDTRONIC failed to accurately disclose the significant off-label risks of which it knew or should have known.

12. Because of MEDTRONIC's wrongful conduct in actively and illegally promoting the off-label use of Infuse® and because of MEDTRONIC's additional wrongful conduct in minimizing, concealing, and downplaying the true risks of these non-FDA-approved, off-label uses of its product, Infuse®, thousands of spine patients, including Plaintiff, underwent surgeries without knowing the true risks inherent in the off-label use of Infuse®.

13. These patients and their physicians relied on MEDTRONIC's false and misleading statements of material fact including statements and publications by MEDTRONIC's "opinion leaders" or "thought leaders" and sales representatives. MEDTRONIC orchestrated a marketing campaign from at least 2002 through 2012 to persuade spine surgeons to use Infuse® in dangerous off-label uses in the spine. Indeed, absent MEDTRONIC's extensive off-label

promotion campaign, physicians like Plaintiff's spine surgeon would never have performed these risky off-label procedures.

14. As a result of Plaintiff's off-label Infuse® surgery using off-label procedures and/or components, Plaintiff suffered the bodily injuries and damages described herein.

PARTIES

15. Plaintiff ROBERT SKOUBO is an individual who is a citizen and resident of Boardman, Oregon.

16. Plaintiff DIANE SKOUBO was and is at all relevant times the lawful spouse of ROBERT SKOUBO and is a resident of Boardman, Oregon.

17. Defendant MEDTRONIC, INC. is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

18. Defendant MEDTRONIC SOFAMOR DANEK USA, INC. is a Tennessee corporation, with its principal place of business at 1800 Pyramid Place, Memphis, Tennessee 38132.

JURISDICTION AND VENUE

19. This court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332, because there is complete diversity of citizenship between Plaintiffs and the Defendants, and because Plaintiffs allege an amount in controversy in excess of $75,000, exclusive of interest and costs.

20. The court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of Oregon. At all relevant times the MEDTRONIC Defendants transacted, solicited, and conducted business in Oregon through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Oregon.

21. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a) because a substantial portion of the wrongful acts upon which this lawsuit is based occurred in this District. Venue is also proper pursuant to 28 U.S.C. § 1391(c), because Defendants are all corporations that have substantial, systematic, and continuous contacts in the State of Oregon, and they are all subject to personal jurisdiction in this District.

FACTS

I. SUMMARY OF ALLEGATIONS

A. Generally

22. At all relevant times, Infuse® was researched, developed, manufactured, marketed, promoted, advertised, sold, and distributed by the MEDTRONIC Defendants.

23. Plaintiff ROBERT SKOUBO suffered grievous personal injuries as a direct and proximate result of Defendants' misconduct.

24. In off-label lumbar or cervical spine surgeries, Infuse® often leads to serious complications including, but not limited to, chromic permanent radiculitis and other nerve injuries, uncontrolled bone growth, osteolysis, and poorer overall outcomes.

B. MEDTRONIC's Representations

25. At all relevant times, the MEDTRONIC Defendants negligently manufactured, marketed, advertised, promoted, sold and distributed Infuse® as a safe and effective device to be used for spinal fusion surgery. MEDTRONIC negligently, recklessly, and/or intentionally promoted Infuse® for off-label use to physicians and spine patients, including the Plaintiff and Plaintiff's physicians, and downplayed to physicians and spine patients its dangerous effects, including

but not limited to the downplaying of the dangerous effects of Infuse® in off-label spine surgeries such as that performed on the Plaintiff.

26. At all relevant times, the MEDTRONIC Defendants misrepresented the safety of Infuse® to physicians and patients, and recklessly, willfully, and/or intentionally failed to alert physicians and patients of the significant danger to patients resulting from the off-label uses of Infuse®.

C. MEDTRONIC's Knowledge

27. MEDTRONIC and its agents knew or should have known and/or recklessly disregarded the materially incomplete, false, and misleading nature of the information that they caused to be disseminated to the public and to spine surgeons regarding Infuse® and including MEDTRONIC's surreptitious campaign to promote the product for off-label uses (i.e., uses not approved or even evaluated by the FDA). The scheme described herein could not have been perpetrated over a substantial period of time, as has occurred here, without the knowledge and complicity of personnel at the highest level of MEDTRONIC, including its corporate officers.

28. At all relevant times, MEDTRONIC knew and/or had reason to know that Infuse® was not safe for off-label uses in the spine because the device had never been approved for use in the spine, other than for anterior approach lumbar fusion surgeries with the LT-Cage™; and that use without the LT-Cage™ was known by MEDTRONIC to be unsafe and ineffective.

29. At all relevant times, MEDTRONIC knew and/or had reason to know that Infuse® was not safe for off-label use because it had not been approved for off-label use; and its safety and efficacy for off-label use was either unknown, or was known by MEDTRONIC to be unsafe and ineffective.

30. MEDTRONIC's acts to promote off-label use of Infuse®, their knowledge of, but failure to disclose, the growing adverse events associated with the product, MEDTRONIC's continued payments to certain spine surgeon "opinion leaders" to promote off-label uses, repeat FDA regulatory action against MEDTRONIC, two whistleblower lawsuits against MEDTRONIC, a Department of Justice ("DOJ") settlement and resulting Corporate Integrity Agreement, and a United States Senate Finance Committee investigation culminating in a scathing report on MEDTRONIC's improper promotional activities on this product demonstrate a conscious and reckless disregard for the health and safety of spinal patients, including Plaintiff.

31. At all relevant times, MEDTRONIC knew and/or had reason to know that their representations and suggestions to physicians that Infuse® was safe and effective for off-label use were materially false and misleading and that physicians and patients would rely on such representations.

32. MEDTRONIC knew and/or had reason to know of the likelihood of serious injuries caused by the off-label use of Infuse® in the spine, but they concealed this information and did not warn Plaintiff or Plaintiff's physicians, preventing Plaintiff and his physicians from making informed choices in selecting other treatments or therapies prior to Plaintiff's implantation surgery and preventing them from timely discovering Plaintiff's injuries.

33. The prevailing best scientific and medical knowledge, as discussed *supra*, demonstrated prior to the date of Plaintiff's injury that off-label use of Infuse® was likely to cause the Plaintiff's injuries as stated herein. This prevailing scientific and medical knowledge was known or knowable by MEDTRONIC for at least a year or more prior to Plaintiff's off-label Infuse® surgery.

D. MEDTRONIC's Off-Label Promotion

34. MEDTRONIC had knowledge and information reflecting the true risks and dangers to spine patients of off-label Infuse®, the extent of the off-label use, and their reckless promotion of the off-label uses. Despite this knowledge, MEDTRONIC knowingly and recklessly conducted an egregious off-label promotion campaign to the detriment of the spine patients, including the Plaintiff.

35. MEDTONIC and its agents encouraged the off-label promotion of Infuse® described throughout this Complaint, notwithstanding their knowledge of the serious adverse events that patients could, and did, suffer, which have often resulted in the need for additional surgery, emergency intervention, and, in at least one case, the death of a patient.

36. MEDTRONIC improperly promoted and marketed Infuse® to Plaintiff's implanting surgeon for off-label use in the spine, and this improper promotion and marketing improperly influenced Plaintiff's spine surgeon's decision to implant Infuse® in Plaintiff's spine in an off-label procedure.

37. MEDTRONIC, as herein described, directly and indirectly promoted, trained, and encouraged Plaintiff's surgeon to perform Plaintiffs' spinal fusion procedure utilizing Infuse® in a dangerous off-label manner.

38. The MEDTRONIC Defendants recklessly and/or fraudulently promoted and marketed Infuse® to Plaintiff and Plaintiff's physicians for off-label use in the spine.

E. Failure to Warn

39. At all relevant times, MEDTRONIC misrepresented the safety of Infuse® to physicians and spine patients, including to Plaintiff and Plaintiff's physicians, and recklessly, willfully, or

intentionally failed to inform Plaintiff and Plaintiff's physicians of the significant dangers to patients resulting from the off-label use of Infuse®.

40. Any warnings MEDTRONIC may have issued concerning the dangers of off-label uses of Infuse® or regarding specific risks of those uses were insufficient or negated in light of MEDTRONIC's contradictory prior, contemporaneous, and continuing illegal promotional efforts and promotion of Infuse® for non-FDA-approved, off-label uses in the spine and contemporaneous efforts to hide or downplay the true risks and dangers of the off-label uses of Infuse®.

F. Causation

41. Plaintiff ROBERT SKOUBO would not have consented to be treated with the off-label use of Infuse® had he known of or been informed by MEDTRONIC or by his spine surgeon of the true risks of the off-label use of Infuse®.

42. Plaintiff and Plaintiff's spine surgeon relied on MEDTRONIC's misrepresentations regarding the safety and efficacy of Infuse® in Plaintiff's spine surgery. Plaintiff and Plaintiff's spine surgeon did not know of the specific risks and/or were misled by MEDTRONIC, who knew or should have known of the true risks but consciously chose not to inform Plaintiff or his spine surgeon of those risks and to actively misrepresent those risks to the Plaintiff and Plaintiff's physicians.

43. MEDTRONIC's off-label promotion and marketing caused Plaintiff's spine surgeon to decide to implant Infuse® in Plaintiff's spine using an off-label approach.

44. Plaintiff's spine surgeon received and relied on MEDTRONIC's improper promotion of the off-label uses, and MEDTRONIC's inadequate warnings which hid or downplayed the risks of off-label use of Infuse®. Plaintiff's spine surgeon would not have done the procedure using

Infuse® off-label (or using Infuse® at all) in the absence of MEDTRONIC's false and misleading promotion of the off-label uses.

G. Alter Ego

45. At all times herein mentioned, each of the defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venture of each of the other defendants named herein and was at all times operating and acting within the purpose and scope of said agency, service, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

46. At all times herein mentioned, Defendants were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and all Defendants and each of them, thereby ratified these actions.

47. There exists and, at all times herein mentioned there existed, a unity of interest in ownership between certain Defendants and other certain Defendants, such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter-ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

48. At all times herein mentioned, the MEDTRONIC Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing,

processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling products for use by the Plaintiff and Plaintiff's physicians. As such, each of the MEDTRONIC Defendants is individually, as well as jointly and severally, liable to Plaintiffs for his/their damages.

49. The harm which has been caused to Plaintiff resulted from the conduct of one or various combinations of the Defendants, and through no fault of the Plaintiff. There may be uncertainty as to which one or which combination of Defendants caused the harm. Defendants have superior knowledge and information on the subject of which one or which combination of the Defendants caused Plaintiff's injuries.

50. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by Plaintiff.

II. THE INFUSE® DEVICE AND SPINAL FUSION SURGERY GENERALLY

51. MEDTRONIC designed and marketed Infuse® for lumbar spine fusion surgery. Similar to the concept of welding, spinal fusion surgery uses bone grafts to join vertebrae together and eliminate or reduce movement between vertebrae.

52. Spinal fusion is used to treat a number of conditions, including treatment of a fractured vertebra, spinal deformity (spinal curves or slippages), back pain from instability, or abnormal or excessive movement between vertebrae.

53. For years, autologous bone graft has been considered the "gold standard" in fusion surgery. In an autologous bone graft—or "autograft"—the surgeon procures bone graft material from another part of the patient's body, typically from the patient's pelvis or iliac crest or from the patient's own spine (from the parts of one or more vertebrae removed to gain access to the disc space to perform the fusion), and implants the bone graft in the site where fusion is desired.

Successful fusions occur at very high rates in autograft procedures, as the harvested bone exhibits all the properties necessary for bone growth (including osteogenic, osteoconductive and osteoinductive properties).

54. As an alternative to autograft, patients can undergo a procedure using allograft, cadaver bone. Although healing and fusion is not as predictable when using allograft as when using autograft (the patient's own bone), an allograft eliminates the need for the harvest procedure required to use autograft.

55. A newer option to traditional bone graft procedures is bio-engineered and bio-manufactured bone-growth materials, including Infuse®. Infuse® and similar materials were thus (at least initially) appealing to many spine surgeons, since they can eliminate the need for harvesting autograft from the patient's own body.

56. Infuse® is a genetically engineered material containing a bone morphogenetic protein (rhBMP-2) and is used as an alternative or supplement to autograft and allograft to help fuse the vertebrae in the spine as part of the spinal fusion surgery. The purpose of Infuse® is to accomplish the same clinical outcomes as grafting a patient's own bone into these locations but without the need to harvest bone from the patient's hip or spine.

57. MEDTRONIC's Infuse® product consists of (1) a metallic spinal fusion cage (the LT-Cage™); (2) the bone graft substitute which consists of liquid rhBMP-2 (derived from Chinese hamster cells); and (3) an absorbable collagen sponge (ACS) which holds the protein and is then placed inside the cage.

58. The fusion cage component maintains the spacing and temporarily stabilizes the diseased region of the spine, while the Infuse® bone graft component is used to form bone, which is intended to permanently stabilize (fuse) this portion of the spine.

59. During this surgery, rhBMP-2 is placed onto and is intended to bind with the absorbable collagen sponge, which is designed to resorb, or disappear, over time. As the sponge dissolves, the rhBMP-2 stimulates the cells to produce new bone.

60. Certain bone morphogenetic proteins ("BMP"s) have been studied for decades because of their ability to heal bone and potentially decrease or eliminate the need for bone graft harvesting from other parts of the body.

61. Scientists isolated the gene for one protein (rhBMP-2) from bone tissue and used molecular biology techniques to create genetically engineered cells. These cells then product large quantities of rhBMP-2. A similar process is used to manufacture other proteins, such as insulin.

62. Attempting to seize on this potentially lucrative opportunity to develop a new spinal fusion method, Sofamor Danek Group, Inc., a Memphis, Tennessee-based spinal device maker ("Sofamor Danek"), acquired the exclusive rights to rhBMP-2 for spinal applications in February of 1995. The rhBMP-2 liquid bone protein sold as Infuse® is a genetically engineered version of a naturally occurring protein that stimulates bone growth, developed as a commercially viable bone morphogenetic protein ("BMP") technology.

63. In October of 1996, Sofamor Danek filed with the FDA an application for an Investigational Device Exemption to conduct a pilot study on the effects of rhBMP-2 in humans, completing the first step to obtaining approval to commercially market the BMP.

64. In January of 1999, MEDTRONIC purchased Sofamor Danek for $3.6 billion. On July 2, 2002, the FDA approved Infuse®, a medical device containing an absorbable collagen sponge that is treated with rhBMP-2, for one limited and very specific spinal fusion procedure with the LT-Cage™.

III. FDA APPROVAL OF INFUSE®

A. The Premarket Approval Process

65. The current regulatory framework for medical device approval was established in the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"). The MDA contains a three-class classification system for medical devices. Class I devices pose the lowest risk of consumers' heath, do not require FDA approval for marketing, and include devices such as tongue depressors. Class II devices pose intermediate risk and often include special controls including post-market surveillance and guidance documents. Finally, Class III devices pose the greatest risk of death or complications and include most implantable surgical devices such as cardiac pacemakers, coronary artery stents, automated external defibrillators, and several types of implantable orthopedic devices for spine and hip surgery. Infuse® is a Class III device.

66. Manufacturers such as the MEDTRONIC Defendants seeking to market Class III devices, such as Infuse®, are required to submit a Premarket Approval Application ("PMA") that must be evaluated and approved by the FDA. The PMA requires the manufacturer to demonstrate the product's safety and efficacy to the FDA through a process that analyzes clinical and other data, including (1) technical data and information on the product, including non-clinical laboratory studies and clinical investigations; (2) non-clinical laboratory studies that provide information on microbiology, toxicology, immunology, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests of the device— all of which must be conducted in compliance with federal regulations which set forth, *inter alia*, criteria for researcher qualifications, facility standards and testing procedures; and (3) clinical investigations in which study protocols, safety and effectiveness data, adverse reactions and complications, device

failures and replacements, patient information, patient complaints, tabulations of data from all individual subjects, results of statistical analyses, and any other information from the clinical investigations are provided, including the results of any investigation conducted under an Investigational Device Exemption ("IDE").

67. A PMA requires that all pertinent information about the device be articulated in the application and requires the manufacturer to specify that medical device's "intended use." The indications for use required on the label are based on the nonclinical and clinical studies described in the PMA. Indications for use for a device include a general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for whom the device is intended.

68. In addition, each PMA submission must include copies of all proposed labeling for the device, which must comply with federal requirements. Specifically, the label must include the common name of the device, quantity of contents, the name and address of the manufacturer, as well as any prescription use restrictions, information for use (including indications, effects, routes, methods, frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions), instructions for installation and operation, and any other information, literature, or advertising that constitutes "labeling" under the FDCA. Approval of the product's labeling is conditioned on the applicant incorporating any labeling changes exactly as directed by the FDA. A copy of the final labeling must be submitted to the FDA before marketing.

B. Infuse®'s Limited FDA-Approved Uses

69. In October of 1996, Sofamor Danek submitted an IDE to the FDA to study the use of rhBMP-2 as applied to an absorbable collagen sponge inserted into an LT-Cage™ interbody fusion

device to treat patients with degenerative disc disease. Designed as a pilot study intended to support the initiation of a larger pivotal study, the IDE involved 14 patients, 11 of which received spinal fusion procedures using the rhBMP-2/ACS/LT-Cage™ device and 3 who received the LT-Cage™ with autologous bone. This study marked the first time rhBMP-2 was used in patients undergoing spinal fusion. In this initial clinical trial, all 11 patients who had been implanted with rhBMP-2 achieved successful fusion within six months from the time of surgery.

70. Sofamor Danek used the results of the pilot study to petition the FDA to initiate a pivotal trial of rhBMP-2 with the LT-Cage™. This trial, which was approved by the FDA in 1998, involved 135 investigational patients who had rhBMP-2 implanted in a single-level Anterior Lumbar Interbody Fusion (ALIF) procedure and 135 control patients who underwent the same procedure using autologous bone graft instead of rhBMP-2.

71. After acquiring Sofamor Danek in 1999, MEDTRONIC filed the Infuse® PMA on January 12, 2001, and was granted expedited review status by the FDA.

72. As presented in MEDTRONIC's original PMA (eventually approved by the FDA in July 2002), the initially-approved Infuse® product consisted of two components:

    a. A specific type of spacer (the LT-Cage™ Lumbar Tapered Fusion Device) component, which is a thimble-sized hollow metal cylinder, which keeps the two vertebrae in place and provides a frame that contains and directs the development of new bone growth; and

    b. The Infuse® Bone Graft Component, which includes a collagen sponge that acts as a carrier and scaffold for the active ingredient in Infuse®, and rhBMP-2, the actual active

ingredient that is reconstituted in sterile water and applied to the collagen sponge before it is placed inside the spacer cage.

73. According to the label sought by MEDTRONIC in the PMA and subsequently approved by the FDA, Infuse® can only be used in an ALIF procedure, involving a single-level fusion in the L4-S1 region of the lumbar spine.[1] ALIF is performed by approaching the spine from the front through an incision in the abdomen.

74. On July 2, 2002, the FDA approved Infuse® to treat degenerative disc disease, but only by means of one specific procedure, namely, anterior lumbar interbody fusion (ALIF) surgeries on a single level between L4 and S1.

75. Importantly, the initial approved labeling for the product indicates in bold, underlined formatting: **"These components must be used as a system. The Infuse® Bone Graft component must not be used without the LT-Cage™ Lumbar Tapered Fusion Device Component."** The labeling also directs the specific manner in which both components are to be used in a fusion procedure.

76. Despite the fact that the FDA only approved rhBMP-2 for use in the spine in combination with use of the LT-Cage™, MEDTRONIC sells Infuse® separately from the LT-Cage™ and has done so continuously since the approval in 2002.

[1] While the product's label remains substantially the same as that approved by the FDA in 2002, the FDA has made minor amendments to the label through post-approval supplements. For example, on July 29, 2004, the FDA approved a supplement expanding the indicated spinal region from L4-S1 to L2-S1. Infuse® has been approved by the FDA for only two other uses: certain oral maxillofacial surgeries and repair of tibial fractures that have already been stabilized with IM nail fixation after appropriate wound management, though these two uses account for a very minor percentage of the product's overall sales.

77. Infuse® has never been approved by the FDA for use in other parts of the boy or for use in any other type of procedure, other than the two non-spinal uses as noted in footnote 1. Any such uses are thus, by definition, "off-label," experimental uses which are not approved by the FDA.

78. There are numerous lumbar and cervical spine procedures for which Infuse® was not initially approved and for which it has never subsequently been approved. No cervical fusion procedure whatsoever using Infuse® has ever been approved by the FDA, regardless of the approach or procedure. The non-approved lumbar procedures include, but are not limited to:

    a. Posterior Lumbar Interbody Fusion ("PLIF"), a procedure that is used to treat nerve compression and back pain resulting from a number of causes, involves approaching the spine from the back. PLIF, however, is a more delicate surgical approach in some respects because the spinal canal and nerves are posterior to the vertebral body, and because a surgeon must manipulate the dural sac (the membranous sac that encases the spinal cord within the vertebral column) to perform the PLIF procedure;

    b. Posterolateral Fusion ("PLF") which is similar to the PLIF procedure, but instead of removing the disc space and replacing it with a bone graft, the disc space remains intact and the bone graft is placed between the transverse process in the back of the spine. This allows the bone to heal and stabilizes the spine by fusing the transverse process of one vertebra to the transverse process of the next vertebra; and

    c. Transforaminal Lumbar Interbody Fusion ("TLIF"), which is also similar to the PLIF procedure, and is a technique utilized when an interbody fusion is performed via a posterior approach without disturbing the dural sac by approaching the spine via a more lateral, or sideways approach.

IV. OFF-LABEL USE OF INFUSE®, RISKS ASSOCIATED WITH OFF-LABEL USES, AND MEDTRONIC'S KNOWLEDGE OF SUCH RISKS

A. Generally

79. Physicians may use FDA-approved medical devices in any way they see fit— either on-label or off-label— but medical device companies are prohibited by federal law from promoting off-label uses for their medical devices or from paying doctors inducements or kickbacks to promote off-label uses, or from performing procedures using the devices off-label. When a physician wishes to use a medical device in an off-label manner, he or she must inform the patient of the off-label nature of the surgery and the expected health risks and benefits of such off-label use, and obtain the patient's informed consent to such use.

B. FDA's Initial Concerns with Infuse®'s Off-Label Uses

80. The FDA's approval of Infuse® was limited to one specific lumbar procedure (the ALIF procedure) due to FDA's concerns about potential adverse events in posterior uses that had already been reported at the time of the product's approval. As a result, the FDA approved Infuse® for the small percentage of overall spinal fusion surgeries which are ALIF procedures, with the device label specifying this limited surgical application.

81. FDA approval of Infuse® was limited to ALIF only because of adverse events resulting from the use of rhBMP-2 in off-label applications. In particular, a MEDTRONIC-sponsored trial examining the application of rhBMP-2 in off-label PLIF (Posterior Lumbar Interbody Fusion) procedures was halted in December 1999 when uncontrolled bone growth developed in a number of patients. Indeed, the study reported that one patient required two additional surgeries to remove excess bone growth from the spinal canal. Such bone overgrowth observed in this PLIF trial was particularly alarming because it could, and did in many patients, result

in worsening the very pain that the fusion procedure was designed to eliminate, and in some cases necessitating difficult revision surgeries to remove the bone overgrowth.

82. Moreover, the 1999 PLIF trial demonstrated that bone overgrowth complications from Infuse® resulted from the product's very mechanism of action, i.e., rhBMP-2 stimulates the growth of new bone. Thus adverse events can result when the rhBMP-2 leaks out of the area in which bone growth is desired and/or when too much rhBMP-2 is used. In such cases, Infuse® can stimulate bone growth where new bone is not desired or can lead to excessive bone growth in the target area, which is often associated with other complications such as swelling, compression of nerves, and associated additional or new pain. Such unintended bone growth and swelling can be especially problematic in spinal surgeries because of the proximity to sensitive neurological structures, i.e., the spinal cord and the exiting nerve roots.

83. During the FDA Advisory Committee Panel ("FDA Panel") hearing on January 10, 2002, concerning potential FDA approval of Infuse®, panel members voiced concerns regarding potential off-label use of the product and asked MEDTRONIC to describe its efforts to guard against off-label use of the product.

84. In response to FDA concerns regarding off-label applications, one MEDTRONIC consultant, who is alleged to have received hundreds of thousands of dollars in the form of kickbacks from consulting agreements promoting Infuse®, dismissed the FDA Panel's concerns, stating, "this specific application before the panel today is through an anterior approach," and accordingly, "seems to me to be outside the scope of what we ought to be focusing on today."

85. Reiterating its concerns regarding off-label use, the FDA Panel cautioned MEDTRONIC to guard against procedures outside the specifically approved ALIF procedure provided in the labeled application. The FDA Panel's admonishment included concerns voiced by panel

member Dr. John Kirkpatrick that off-label use could result in harm to patients. More specifically, the use of the *tapered* LT-Cage™— which is difficult to implant in a posterior approach— would, if required, "prevent a majority of surgeons from applying this from a Posterior Lumbar Interbody Fusion [PLIF] perspective." In other words, the FDA explicitly warned MEDTRONIC against promoting Infuse® for use in off-label PLIF procedures because, according to the statements of the FDA Panel, such use could endanger patients.

86. At the conclusion of the hearing, the FDA Advisory Panel again reiterated concerns regarding the potential for off-label use, specifically admonishing the MEDTRONIC Defendants to guard against procedures other than the specific ALIF (anterior lumbar interbody fusion) procedure approved by the FDA.

C. Off-Label Use of Infuse® is Dangerous and Causes Adverse Side Effects.

87. The off-label use of Infuse® in the spine frequently causes serious adverse events. This has been known to MEDTRONIC and its key "opinion leaders" for many years.

88. The FDA Panel's initial fears in 2002 concerning the dangers of off-label use of this product were confirmed by subsequent medical studies which demonstrate that off-label use of Infuse® may present severe risks and dangers to patient safety.

89. For example, an early study sponsored and funded by MEDTRONIC in 1999 (mentioned *infra*) demonstrated an approximately 70% rate of ectopic bone growth. Only a few months into this clinical trial of Infuse®, CT scans showed unwanted bone had already formed in the spinal canals of 70% of the patients treated with Infuse®. This clinical trial, intended to include hundreds of people with degenerative disc disease, was halted after only 34 patients received Infuse®.

90. A spine surgeon who participated in this PLIF study involving Infuse® reported that one of the patients he treated required two extra surgeries to clear the excessive bone growth from the patient's spinal canal. The complications observed in this PLIF trial were particularly serious given the potential of neural impingement (or nerve pinching) from such bony overgrowth in that procedure, potentially triggering the very sort of pain that a fusion procedure is intended to eliminate.

91. This bone overgrowth results from Infuse®'s very mechanism of action. In such cases, Infuse® can stimulate bone growth where new bone is not desired and can lead to excessive bone growth into area where bone should not be growing— i.e., into or against the spinal cord or other spinal nerves.

92. There is insufficient scientific evidence concerning the proper dosages of rhBMP-2 for use in the off-label procedures such as PLIF, TLIF, PLF and cervical fusions. The expected response to the protein varies in different biological environments. Many adverse events associated with the use of Infuse® result from the off-label use of the product by surgeons who do not fully understand the highly potent nature of this molecule.

93. Astonishingly, it was not until 2004 that a paper about the disastrous 1999 PLIF trial by spine surgeons with financial ties to MEDTRONIC was finally published in a medical journal. This article inaccurately maintained that these patients were not harmed by Infuse®. The paper (Haid, et al., *Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages, The Spine Journal*, 4(5):527-538, September 2004) downplayed the bone overgrowth complications, claiming that while bony overgrowth showed up on CT scans, patients did not suffer ill effects. This claim was false and misleading and further encouraged dangerous off-label uses of Infuse®.

94. In fact, David Malone, M.D., a Tulsa, Oklahoma spine surgeon involved in this 1999 PLIF clinical trial with Infuse®, told the *Milwaukee Journal Sentinel* that two of his patients had to undergo additional surgeries because the BMP-induced bone overgrowth was painfully impinging on their nerve roots. One of the patients, a man who was in his 50s at the time, needed three operations— one for the implant, a second to remove the unwanted bone formation, and a third when the additional bone grew back yet again.[2]

95. "It was a pretty amazing biological response," Dr. Malone said in an interview. "It grew back even larger than the first time. It got to the point that secretaries in our clinic could look at X-rays and tell who got the BMP (Infuse) and who did not. You could see that much bone growth."[3]

96. A May 15, 2006 medical article in *Spine* entitled "Controlling Bone Morphogenetic Protein Diffusion and Bone Morphogenetic Protein-Stimulated Bone Growth Using Fibrin Glue" observed, "rhBMP-2 may stimulate bone growth in areas in which bone is not desired, especially as the material 'leaks' into such spaces…Although this phenomenon has not been thoroughly studied, it implies that the release of BMP-2 into the soft tissues stimulates a rapid, potentially life-threatening, inflammatory reaction."[4]

97. Again, in a November 2006 issue of *Spine*, several authors noted a significantly increased risk of swelling from off-label use of Infuse® in cervical spine fusions compared to traditional fusion surgeries. Of the 234 patients studied, 27.5% of those patients treated with Infuse® had significant swelling after the surgery, while only 3.6% of those patients not treated with Infuse®

---

[2] *See, e.g.*, "Infuse® Cited in Pateints' Painful Bone Overgrowth: More Surgery Needed After Use, Surgeon Says," by John Fauber, *Milwaukee Journal Sentinel*, June 27, 2011.
[3] *Id.*
[4] Patel, et al., *Controlling Bone Morphogenetic Protein Diffusion and Bone Morphogenetic Protein-Stimulated Bone Growth Using Fibrin Glue, Spine,* 31(11): 1201-1206, May 2006.

experienced such a complication. Further analysis demonstrated that "patients receiving rhBMP-2 were ***10.1 times more likely*** to have a swelling complication versus those who did not receive rhBMP-2." (Emphasis added.)[5]

98. A March 2007 article in *The Spine Journal* highlighted the severity of the complications associated with off-label use of Infuse®. According to this article, five days after Infuse® was implanted off-label in a cervical spine fusion surgery, the implanted patient experienced severe swelling of the neck and difficulty swallowing which required emergency medical treatment such as an exploratory surgery and implantation of a breathing tube.[6]

99. A *European Spine Journal* article in August 2007 found that use of Infuse® in certain cervical spine fusions resulted in a statistically significant increase in the number of complications, including dysphagia (difficulty in swallowing) and swelling in the neck area. The authors determined that "[d]ysphagia was a common complication and it was significantly more frequent and more severe in patients in whom rhBMP-2 was used. Post-operative swelling…was significantly larger in the rhBMP-2 group." Of the patients evaluated, 85% of those treated with Infuse® reported difficulty swallowing after the surgery; a complication that was far less prevalent in those not treated with Infuse®. Indeed, one patient required a feeding tube for six weeks after the surgery as a result of the complication.[7]

100. On July 1, 2008, the FDA issued a Public Health Notification to healthcare practitioners entitled, "Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion" (the "FDA Notification"), which strongly

---

[5] Smucker et al., *Increased Swelling Complications Associated with Off-Label Usage of rhBMP-2 in the Anterior Cervical Spine, Spine,* 31(24):2813-2819, November 2006.
[6] Perri, et al., *Adverse Swelling Associated with Use of rhBMP-2 in Anterior Cervical Discectomy and Fusion: A Case Study, The Spine Journal*, 7(2): 235-239, March 2007.
[7] Vaidya, et al., *Complications of Anterior Cervical Discectomy and Fusion Using Recombinant Human Bone Morphogenetic Protein-2, European Spine Journal*, 16(8): 1257-1265, March 2007.

warned medical professionals who used Infuse® and other BMP products of serious complications that had occurred from the off-label use of these products in the cervical spine.[8]

101. The FDA Notification stated that the agency had received numerous reports of complications from BMP use in the cervical spine that "were associated with swelling of neck and throat tissue," which resulted in compression of the airway and/or neurological structures in the neck. Some reports describe difficulty swallowing, breathing or speaking." The notification further stated that these complications had resulted in "the need for emergency medical intervention," which included "respiratory support with intubation, anti-inflammatory medication, tracheotomy and most commonly second surgeries to drain the surgical site." The FDA Notification concluded that "in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies."

102. On September 4, 2008, *The Wall Street Journal* published a front-page article entitled "MEDTRONIC Product Linked to Surgery Problems."[9] This article noted both the complications resulting from the use of Infuse® in the cervical spine already disclosed in the FDA Notification and additional complications resulting from other off-label applications of the product, stating:

> The FDA's alert about Infuse® was specific to neck surgeries. But a review of FDA records and medical literature shows there have been scores of other cases in which serious complications arose after the product was used in other off-label situations. Many of these cases involve unwanted bone growth near nerves or in areas outside of targeted fusion sites. That can lead to pain, repeat surgeries and, in some cases, emergency intervention.

[8] FDA Public Health Notification: Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion, July 1, 2008, http://www.fda.gov/MedicalDevices/safety/alertsandnotices/publichealthnotifications/ucm062000.htm.

[9] "Medtronic Product Linked to Surgery Problems," David Armstrong and Thomas M. Burton, *Wall Street Journal*, September 4, 2008.

The article further stated that at least three-quarters or 75% of the adverse events reported to the FDA involved off-label use of Infuse®. Of course, the news had serious implications for MEDTRONIC, because off-label use of Infuse® accounted for the majority of all Infuse® sales.

103. A September 2008 article in *The Spine Journal* also observed that the use of Infuse® in the cervical spine "has been associated with reports of serious adverse events."[10] Postoperative hematoma formation [a collection of blood outside the blood vessels, generally manifesting as bruises], prevertebral soft tissue swelling, [and] swallowing difficulty…are a few examples." Of the complications observed in this patient study group, 17% occurred in patients treated with traditional techniques, while 83% occurred in patients treated off-label with Infuse®. The authors concluded that the "cervical spine has proven much less forgiving with the institution of rhBMP-2 use. Complications induced by…rhBMP-2 were clearly evident in our review."

104. On November 18, 2008, in connection with reporting MEDTRONIC's financial results for its 2009 second quarter (ended October 24, 2008), MEDTRONIC reported that revenue from its Spinal segment had, in fact, declined to $829 million for the quarter— down $30 million from the previous quarter. The decreased sales in the Spinal segment, clearly stemming from a significant decline in Infuse® sales, were a sharp deviation from MEDTRONIC's reports of repeated, double-digit growth in the Spinal segment in previous quarters. Moreover, MEDTRONIC disclosed, for the first time, that it "recently received a subpoena from the Department of Justice, looking into off-label use of Infuse®.

105. Thereafter, MEDTRONIC continued to report lower sales of Infuse®, which it admittedly linked to (a) a public health notice from the FDA regarding off-label use of rhBMP-2 in the

[10] Jarosz, et al., *Complications of BMP Use in Cervical Spine Surgery, The Spine Journal* 8(5): 23S-24S, September 2008.

cervical spine that was issued in July 2008; (b) a previously disclosed government investigation, negative newspaper stories; and (c) a whistleblower lawsuit filed by two former MEDTRONIC employees against MEDTRONIC and a number of spine surgeons and distributors of the Infuse® bone graft.

106. A study entitled "Prevalence, Complications, and Hospital Charges Associated with the Use of Bone Morphogenetic Proteins in Spinal Fusion Procedures," Cahill, et al., *JAMA*, 2009 Jul 1;302(1):58-66, analyzed the integration of BMP into spinal surgeries since 2002 and the association between its use and postoperative complications, length of hospital stays, and hospital charges. Significantly, the study determined that the use of bone morphogenetic proteins is associated with a substantially higher rate of complications in anterior cervical fusion procedures, which has resulted in an approximate 41% increase in hospital charges for those procedures. Notably, the study only considered complications that occurred during postoperative inpatient hospitalization immediately following the surgical procedure, and did "not include delayed complications in the outpatient setting," such as hospital readmission-related complications.

107. Such a shortcoming likely resulted in a significant understatement of the extent of complications resulting from use of bone morphogenetic proteins because, as an FDA Public Health Notification regarding complications from use of BMP in the cervical spine indicated, "[m]ost complications occurred between 2 and 14 days post-operatively with only a few events occurring prior to day 2." Indeed, acknowledging this fact, Dr. Kevin S. Cahill, who led the study, publicly commented, "ours is probably a bottom estimate."

108. Aside from potential understatement of complications, the study found that the rate of complications in anterior cervical fusions was 51.4% higher when using bone morphogenetic

protein than in similar cases when bone morphogenetic protein was not used. These complications included increased rates of voice and swallowing-related problems and swelling of the neck. The study's authors noted a "significantly greater" rate of complications when using bone morphogenetic proteins in these surgeries, even after considering and compensating for numerous other variables that could affect complications rates, such as age, sex, etc.

109. At least 1,200 reports of adverse events involving Infuse® have been made to the FDA from 2002 through 2011. In 2011, for example, 278 Infuse®-related adverse events were reported; in 2010, 362 adverse events were reported; and in 2009, 244 adverse events were reported. The vast majority of these adverse events involve off-label use of Infuse®.

110. In fact, in a 2012 article published in *The Spine Journal*, FDA researcher Emily Woo, M.P.H. concluded on-label use of Infuse® accounts for only a tiny percentage (0.5%) of adverse events. Off-label use of Infuse® accounts for 99.5% of adverse events.[11]

111. The number of Infuse®-related adverse events grew steadily over the years. The proportion of off-label adverse events increases as a direct result of the MEDTRONIC Defendants' long-standing campaign of improper and untruthful off-label promotion of the more dangerous off-label uses of Infuse® which were never approved by the FDA. At all relevant times, the extent of these adverse events was hidden or downplayed by MEDTRONIC and its paid consultants.

D. MEDTRONIC's Prior Knowledge and Concealment of the Dangers of Off-Label Infuse® Uses

[11] Emily Jane Woo, *Recombinant Human Bone Morphogenetic Protein 2: Adverse Events Reported to the Manufacturer and User Facility Device Experience Database, The Spine Journal*, 12(10): 894-899, October 2012.

112. Even at the time of FDA approval, MEDTRONIC and its senior management and its paid consultant "opinion leaders," were well aware of the concerns regarding off-label uses of Infuse® and the serious dangers to patients posed by those off-label uses.

113. Notwithstanding the original FDA Panel's well-founded concerns regarding off-label use, as well as the medical literature's corroboration of the same, both of which MEDTRONIC had knowledge, MEDTRONIC intentionally, negligently and recklessly concealed these dangers from the general public, including Plaintiff and Plaintiff's physicians.

114. MEDTRONIC had actual knowledge of the Advisory Committee's concerns regarding off-label use of the product and the dangers posed by off-label use. Indeed, Defendants were on actual notice of the dangers that off-label use of Infuse® posed to patients, such as the Plaintiff.

115. Further, as described immediately *infra*, the MEDTRONIC-funded studies on Infuse® from 1999 until at least 2007 failed to accurately describe the adverse effects that were observed in the earliest trials of Infuse®, such as severe uncontrolled or ectopic bone growth, severe inflammatory reaction, adverse back and leg pain events, radiculitis, retrograde ejaculation in men, urinary retention, bone resorption, and implant displacement. These MEDTRONIC-funded articles also omitted any mention of the risks of sterility and cancer associated with rhBMP-2 use, as reported in FDA documents and hearings. MEDTRONIC discouraged the publication of these adverse events in the medical journal literature, thereby hiding significant side effects from spine surgeons and patients.

116. Further, Confidential Witness #2 (CW 2") in a shareholder derivative lawsuit filed against MEDTRONIC, more fully discussed *supra*, stated that MEDTRONIC was aware of adverse events resulting from off-label use of Infuse® in the cervical spine, including swallowing and breathing problems.

117. In response to these reports of adverse events, CW 2 stated that MEDTRONIC attempted to disseminate information to the medical community regarding what it considered to be the proper dose of Infuse® for this off-label application. MEDTONIC also issued a "Safety Alert" letter to surgeons on September 14, 2004, informing them that MEDTRONIC had received reports of complications associated with off-label use of Infuse® in anterior cervical fusion procedures. MEDTRONIC wrote, ***"[l]ocalized soft tissue edema has been reported in anterior cervical spine fusion surgery following the use of Infuse® Bone Graft…Some reports were accompanied by patient complaints of swelling and difficulty in swallowing and breathing, three of which resulted in surgical intervention."*** (Emphasis added.)

118. These adverse events were not isolated incidents, as described above. These adverse event reports from off-label uses of Infuse® indicate the very same complications as those noted in the studies discussed above, including swelling, difficulty swallowing and breathing, excessive bone growth resulting in dangerous and painful spinal nerve compression and corresponding injuries, etc., and often require emergency medical intervention or a second surgery.

119. For example, a December 12, 2005 report indicates that four or five days after an off-label PLIF procedure involving Infuse®, a patient's swelling became so severe that surgical intervention was required.

120. A November 3, 2006 report indicates that a patient reported neck swelling, difficulty swallowing and possible shortness of breath two to three days after a cervical spine fusion using Infuse®. As a result, this patient had to undergo another surgery four days after the fusion.

121. A July 21, 2008 report indicates that a patient developed massive neck swelling, very thick tracheal and bronchial secretions, and required a tracheostomy— a procedure in which an

incision is made in the neck and a tube inserted to allow the patient to breathe- following a cervical fusion procedure with Infuse®. These are only a few examples of the hundreds of similar reports of serious complications related to off-label uses of Infuse® found on the MAUDE Database.

122. Through MEDTRONIC's monitoring procedures— which include written procedures for complaints, corrective and preventative actions, and adverse event reporting— all complaints and adverse events are documented, tracked, and trended (or should be) in a database. MEDTRONIC is required by federal regulations to "establish and maintain" such an adverse event database. *See* 21 C.F.R. 801.1(a). In addition, a report from a June 2006 FDA inspection of a MEDTRONIC facility at 1800 Pyramid Place in Memphis, Tennessee, revealed that MEDTRONIC had initiated a Preventative Action, dated April 21, 2006, and was "studding [sic] the reason for an increase in the number of reported fluid collection, hematoma, and seroma complaints since 4/2005." According to the report, the "study indicated that sales for the Infuse® Bone Graph [sic] have increased and more graphs [sic] are being implanted," and that the "study is still open."

123. According to Confidential Witness #15 ("CW 15") in the *Minneapolis Firefighters* lawsuit filed against MEDTRONIC, more fully discussed *supra*, a Senior Vice President who worked at MEDTRONIC for numerous years until 2006 and a "Quality Group" at MEDTRONIC's Spine division were responsible for addressing adverse events. According to CW 15, former COO Michael DeMane, former President of MEDTRONIC Spinal and Biologics Peter Wehrly, and former Worldwide Vice President and General Manager of Biologics John Serbousek, were all aware of the adverse events related to Infuse®. As part of his employment with Defendants, CW 15 discussed the complaints related to Infuse® at meetings with these

individuals and members of the Quality Group to decide whether or not certain adverse events should be reported to the FDA. Moreover, MEDTRONIC's Spinal division used the very same complaint/adverse event reporting system as MEDTRONIC corporate, which provided MEDTRONIC's executive officers access to a database containing the details of every complaint/adverse event MEDTRONIC received relating to Infuse®.

124. MEDTRONIC was further clearly aware of its settlement with the Department of Justice ("DOJ") and entry into a Corporate Integrity Agreement, discussed *supra*, in July of 2006. As a result, MEDTRONIC had actual knowledge of the heightened risks to spine patients associated with MEDTRONIC's illegal, improper, and unethical promotion of off-label use of Infuse® by MEDTRONIC's Spinal or Biologics Divisions.

E. October 25, 2012 U.S. Senate Committee on Finance Report on Medtronic's Manipulation of the Infuse® Studies and Close Financial Ties with Researchers

125. On September 20, 2007, Senator Charles Grassley, as a ranking member on the U.S. Senate Committee on Finance, sent a letter to William Hawkins, III, President and Chief Executive Officer of MEDTRONIC, Inc. The letter raised concerns regarding unlawful payments to physicians to encourage off-label use of Infuse®. Senator Grassley inquired about MEDTRONIC compensating physicians for attending medical conferences, travel arrangements, and various educational activities.

126. MEDTRONIC failed to heed Senator Grassley's warnings and that MEDTRONIC continued to make unlawful payments to physicians in violation of the FDCA.

127. On September 30, 2008, Senator Grassley, in his capacity as ranking member on the U.S. Senate Committee on Finance, sent another letter to CEO William Hawkins, III, again raising concerns about MEDTRONIC's fraudulent promotion of off-label use of Infuse®. In his letter,

Senator Grassley also requested MEDTRONIC's support in passing the Physician Payments Sunshine Act, which, as of March 31, 2013, requires pharmaceutical, medical device, biological, and medical supply manufacturers operating in the United States to report to the Secretary of the United States Department of Health and Human Services all payments (in various forms) or transfers of value made to covered recipients in the prior calendar year.

128. On May 19, 2008, William Hawkins, III responded to Senator Grassley, indicating that MEDTRONIC "supports the Physician Payments Sunshine Act." Mr. Hawkins began by representing, "We have a great deal of confidence that any payments we make to physicians are appropriate and represent fair market value for their services…"

129. MEDTRONIC once again failed to heed Senator Grassley's warnings and that MEDTRONIC continued to make fraudulent and unlawful payments to physicians in violation of the FDCA.

130. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Charles Grassley (R-Iowa) released the results of their 16-month investigation into MEDTRONIC's activities, which revealed questionable ties between the company and its physician "Opinion Leader" consultants tasked with testing and reviewing Infuse®. Without public disclosure of their roles, MEDTRONIC employees collaborated with the physician authors to edit—and in some cases, write— segments of published studies on Infuse®. The Senate report found that MEDTRONIC also maintained significant, previously-undisclosed financial ties with the physicians who authored the early studies on Infuse®, making $210 million in payments to physicians over a 15-year period.

131. "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical

devices, but patients are at serious risk when companies distort the facts the way Medtronic has," Senator Baucus said. "Patients everywhere will be better served by a more open, honest system without this kind of collusion."

132. The report released on October 25, 2012 was the product of an investigation they began in June 2011.[12] The major findings of the investigation include:

a. MEDTRONIC was involved in drafting, editing, and shaping the content of medical journal articles on Infuse® authored by its physician consultants who received significant amounts of money through royalties and consulting fees from MEDTRONIC. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles. Medical journals should ensure any industry role in drafting articles or contributions to authors be fully disclosed.

b. MEDTRONIC paid a total of approximately $210 million to physician authors of MEDTRONIC-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

c. An e-mail exchange shows that a MEDTRONIC employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with Infuse® in a 2005 *Journal of Bone and Joint Surgery* article.

d. MEDTRONIC officials inserted language into studies that promoted Infuse® as a better technique than an alternative by emphasizing the pain associated with the alternative.

F. Further Evidence of MEDTRONIC's Off-Label Promotion

[12] The Senate's full report is available online at http://www.finance.senate.gov/newsroom/chairman/release/?id=b1d112cb-230f-4c2e-ae55-13550074fe86.

133. MEDTRONIC's knowledge and promotion of off-label use of Infuse® is further evidenced by comparing sales of the rhBMP-2 component to the sales of the LT-Cage™ component. (Both components are required to be used together pursuant to the FDA approval.) On information and belief, MEDTRONIC sells the rhBMP-2 component separately from the LT-Cage™ in order to illegally and improperly promote off-label uses of Infuse® in the lumbar spine and in the cervical spine, procedures in which the LT-Cage™ is not used. As a result, sales of the rhBMP-2 component are and were at all relevant times far larger than sales of the LT-Cage™ component, despite the FDA requirements that both be used according to the product's labeling.

134. As described in detail above and throughout this Complaint, therefore, MEDTRONIC's off-label promotion of Infuse® was not truthful. Instead, MEDTRONIC's off-label promotion of Infuse® was false and misleading. "Of course, off-label promotion that is false or misleading is not entitled to First Amendment protection." *United States v. Caronia*, 703 F.3d 149, 165, n.10 (2d Cir., 2012).

135. MEDTRONIC's aggressive off-label promotion described above created the conditions for widespread acceptance by spine surgeons of the off-label uses of Infuse® after the 2002 PMA approval, and MEDTRONIC's violations of federal law described above (which parallel Plaintiff's state-law tort claims) directly caused or significantly contributed to the widespread off-label use of Infuse® generally, and also specifically with respect to Plaintiff. In particular, MEDTRONIC's off-label promotion activities and failure to report adverse events caused spine surgeons, including Plaintiff's surgeon, to use Infuse® in dangerous off-label procedures.

V. INFUSE® IS PROFITABLE AND THUS MEDTRONIC HAD AN ECONOMIC MOTIVE TO PROMOTE INFUSE® OFF-LABEL

136. Infuse® became a best seller for MEDTRONIC. MEDTRONIC's Infuse® sales exceeded $3.6 billion since the launch of the Infuse® Bone Graft in July 2002. As a J.P. Morgan research analyst covering MEDTRONIC noted in a report dated November 12, 2008:

> Infuse® is an $800M product for MEDTRONIC (6% of sales), having enjoyed robust growth since its initial approval in the U.S. in July 2002. In fact, it is the one piece of MEDTRONIC's Spine business that continues to post strong double-digit growth without any issues (LTM: +16.9%). That is, until now.

137. MEDTRONIC has depended heavily on Infuse® sales because so many of its other products, such as cardiac defibrillators, have slowed as the result of recalls of those defective defibrillators in the past several years.

138. Revenue generated by sales of Infuse® was approximately $800 million for the 2011 fiscal year, and the vast majority of these sales were attributable to off-label use of the product. Off-label uses of Infuse® account for 85% to 90% of all spine surgeries involving Infuse®.

139. Plaintiff is informed and believes and based thereon alleges that, as a result of MEDTONIC's illegal, untruthful, and improper off-label promotion, sales of Infuse® have soared and totaled around 4 billion dollars from 2002 through 2011.

140. MEDTONIC has consistently sought to expand the use of Infuse® by, among other things, illegally, untruthfully, and improperly promoting dangerous and/or insufficiently studied off-label uses for Infuse® in various parts of the spine for various types of spine surgeries, as discussed throughout this Complaint.

VI. MEDTRONIC'S FRAUDULENT SCHEME AND ITS USE OF KEY OPINION LEADERS AND OTHER PAID PHYSICIANS TO PROMOTE OFF-LABEL USE OF INFUSE®

A. Off-Label Promotion of Infuse® Violates the Food, Drug, and Cosmetic Act

141. The Food, Drug, and Cosmetic Act ("FDCA") specifically provides that the FDA has no authority to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed [medical] device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship," and physicians are free to prescribe or use medical devices in any manner they deem medically appropriate. 21 U.S.C. § 396.

142. Importantly, however, medical device manufacturers, such as MEDTRONIC, cannot actively promote products for uses not approved by the FDA. Indeed, federal law provides for significant penalties for manufacturers that promote their products in ways inconsistent with a product's labeling. Severe penalties for off-label promotion, such as fines of up to twice the amount of gross pecuniary gain from the offense, were designed to ensure that the FDA's careful, deliberate consideration of a product's suitability for public consumption is not undermined by manufacturers seeking to circumvent that process. The MEDTRONIC Defendants are medical device companies, not physicians, and they were thus prohibited by federal law, including the relevant FDA regulations, at all relevant times, from promoting to physicians or patients any off-label use of Infuse®.

143. Under the FDCA and its accompanying regulations, a device manufacturer must include all intended uses in the label, otherwise the device is misbranded. 21 C.F.R. § 801.4. Under the FDCA, device manufacturers can be held liable for off-label promotion when their products are deemed "misbranded" under the statute. 21 U.S.C. § 331(b).

144. A product is "misbranded" when the directions and indications for the unapproved uses that the manufacturer "intends" the product to be used for have not been included on the label. *See* 21 C.F.R. § 801.4. Further, a device's intended uses are evidenced by the manufacturers'

conduct, not by reference to what the FDA has approved. *Id.* A product's intended uses can be derived from oral statements by persons speaking on behalf of a company about its product. In other words, a manufacturer can be liable under the FDCA if its conduct demonstrates intent to encourage product use inconsistent with or outside the scope of the product's approved label. *Id.*

145. The FDCA's accompanying regulations require that medical devices sold by manufacturers have adequate directions for use, 21 C.F.R. § 801.5, and failure to have adequate instructions for use is considered "misbranding." 21 U.S.C. § 352(f), which is prohibited. 21 U.S.C. § 331(b).

146. The FDCA requires medical device manufacturers to disclose all material facts in advertising and labeling,[13] 21 U.S.C. 321(n), and false or misleading labeling is considered "misbranding," 21 U.S.C. § 352(a), (q)(1), which is prohibited. 21 U.S.C. § 331(b).

147. Further, the FDCA requires medical device manufacturers to maintain and submit information as required by regulation, 21 U.S.C. § 360i, including submitting adverse event reports, 21 C.F.R. § 803.50, and establishing internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198(a).

148. MEDTRONIC violated these FDCA statutes and accompanying regulations by promoting Infuse® for off-label uses, and by failing to account for adverse events and update its labeling, directions for use, and advertising to address the adverse events resulting from these off-label uses.

[13] 21 U.S.C. § 321(m) defines the scope of medical device labeling.

149. MEDTONIC's violation of these FDCA statutes and accompanying regulations, as discussed above, constitutes a violation of the state-law tort causes of action alleged in this Complaint, as set forth below.

150. MEDTRONIC's violation of the FDCA statutes and accompanying regulations, as discussed above, directly caused or significantly contributed to the off-label use of Infuse® generally, and directly caused or significantly contributed to the off-label use of Infuse® in this particular Plaintiff, and MEDTRONIC's misconduct in this regard thus caused or contributed to Plaintiff's injuries or damages.

B. MEDTRONIC's Elaborate, Off-Label Promotion Scheme— Generally

151. In spite of the very specific and limited FDA approval of Infuse® (for ALIF procedures only), the overwhelming majority of MEDTRONIC's Infuse® sales have been driven by non-FDA-approved, or "off-label" uses, such as that used on the Plaintiff in this case.

152. Indeed, MEDTRONIC's unlawful off-label promotion campaign was so extensive that it caught the attention of, among others, the FDA (on numerous occasions), the United States DOJ, Congress, the united States Army, several major universities, multiple medical journals, numerous major newspapers, independent physicians, and investors.

153. Moreover, MEDTRONIC's unlawful off-label campaign has resulted in, among other actions, two whistle-blower lawsuits (resulting in a multi-million dollar settlement with the DOJ, which included a Corporate Integrity Agreement), a shareholder derivative lawsuit that was recently settled for $85 million, several adverse regulatory actions by the FDA, and a congressional investigation (led by the United States Senate Committee on Finance).

154. In 2004, Rick Treharne, who held various vice president positions at MEDTRONIC Sofamor Danek during the relevant time period, e-mailed Scott Boden, a Key Opinion Leader,

with regard to complaints MEDTRONIC had received regarding Infuse® thus far. He noted that "where we have details, which is the majority, all complaints involved off-label use, and for the ones where we don't know much we cannot confirm that the product was used on-label."

155. E-mails disclosed by MEDTRONIC to the United State Senate Committee on Finance demonstrate that a MEDTRONIC employee recommended against publishing a complete list of adverse events possibly associated with Infuse® in an article published in the *Journal of Bone and Joint Surgery* in 2005.

156. Even following MEDTRONIC's settlement with the DOJ in 2006 for unlawful kickbacks to physicians to use and promote its products, and corresponding entry into a Corporate Integrity Agreement ("CIA"), MEDTRONIC failed to disclose its continued reliance on kickbacks, royalties, and other undisclosed payments to physicians to drive Infuse® sales, primarily for off-label use.

157. Off-label use of Infuse® was and remains particularly concerning due to the known adverse (and in at least one case, deadly) side effects known to MEDTRONIC at the time of the product's original FDA approval in 2002. Nonetheless, off-label use of Infuse® increased year after year from the time of its original limited use approval by the FDA in 2002, to the point where off-label use of Infuse® Bone Graft accounted for an astounding 85% to 90% of all Infuse® sales.

158. In order to drive sales of Infuse®, MEDTRONIC engaged in a multi-faceted campaign to promote off-label uses of Infuse® that consisted of the following techniques:

a. Utilizing its sales representatives to promote off-label uses of Infuse® by having the representatives be present in operating rooms during surgery to assist physicians,

distribute the false and misleading medical literature that was written and/or edited by MEDTRONIC, make recommendations concerning dosing, and refer physicians to MEDTRONIC's paid physicians;

b. Utilizing its distributors to purchase gifts for physicians and facilities with the aim of inducing those parties to use Infuse® off-label;

c. Utilizing "Opinion Leaders" and other paid physician consultants to promote off-label uses of Infuse® at conferences, in VIP meetings, hands-on demonstrations, and by having these paid physicians serve as resources for other physicians seeking more information on off-label uses of Infuse®; and

d. Playing an active role in the writing and editing of nearly all published medical literature on Infuse® from at least 2001 through 2006;

159. In this particular case, MEDTRONIC actively promoted the off-label procedures to Plaintiff's spine surgeon. Plaintiff's spine surgeon would not have performed the off-label Infuse® procedure in the absence of such promotion. MEDTRONIC's off-label promotion of Infuse® to Plaintiff's surgeon was false and misleading, because it overemphasized the purported benefits of the off-label use, and minimized, or downplayed the true risks and dangers of the off-label use, all of which were known to MEDTRONIC at all relevant times.

C. MEDTRONIC Promoted Off-label Uses of Infuse® through its Sales Representatives and Distributors

1. *MEDTRONIC's Use of Sales Representatives to Promote Off-label Uses of Infuse®*

160. MEDTRONIC also directed its own sales representatives to promote off-label uses of the product, many of whom went so far as to recommend dosages of this potent molecule in risky off-label procedures, and guide surgeons through off-label uses of the product during surgery.

161. Several spine surgeons have already testified under oath at depositions that MEDTRONIC sales personnel overtly and directly promoted to them the off-label uses of Infuse® in the spine, and Plaintiff is thus informed and believes that MEDTRONIC engaged in a scheme at all relevant times to expand its market share of this product by improperly encouraging such off-label uses.

162. CW 1[14] reported that MEDTRONIC held regional and national sales team meetings during which MEDTRONIC sales representatives received oral instruction on various off-label uses of Infuse® Bone Graft including with regard to how much (or little) rhBMP-2 to use with off-label cervical fusions, so that when doctors questioned sales representatives, they could tell them why and how to use the product off-label. According to CW 1, MEDTRONIC shared this information with the sales representatives orally and there were no marketing documents created by MEDTRONIC for this purpose. Instead, according to CW 1, MEDTRONIC sales representatives were expected to pass on the information they received to doctors orally, without marketing documentation.

163. According to CW 10, who was employed by MEDTRONIC for over five years, including as a Spinal regional sales manager in the Northwest United States from 2002 to 2004, when CW 10 had experience with Infuse® Bone Graft, MEDTRONIC sales representatives would "get around" off-label promotion by directing doctors who inquired about off-label use to others who were using the product "successfully" off-label.

164. According to CW 3, who was employed by MEDTRONIC as a Biologics sales representative in the Mid-Atlantic United States from the end of 2005 through 2008 and specifically promoted sales of the Infuse® Bone Graft product during CW 3's tenure with the

[14] All future references to Confidential Witnesses or "CW" refer to those confidential witnesses cited in the *Minneapolis Firefighters' Relief Association v. MEDTRONIC, Inc.* Complaint.

company, if a doctor asked how to use Infuse® Bone Graft off-label, a MEDTRONIC sales representative would direct the doctor to other surgeons who used the product off-label and also would demonstrate or explain how to do so. CW 3 stated, for example, that if a doctor was going to use Infuse® Bone Graft in the lateral gutter (the area of the spine adjacent to the lateral, or side, edge of the dural sac), a MEDTRONIC sales representative would show the doctor how to place the rhBMP-2 material and roll the ACS sponge up "like a burrito" to place into the lateral spine. According to CW 3, a MEDTRONIC sales representative would be in the operating room to show the doctor how to assemble the sponge or to explain other procedures.

165. According to CW 5, who was employed by MEDTRONIC as an associate sales representative in various regions of the country—including the South, Southwest, and Midwest—from 2005 until 2006 and specifically promoted sales of the Infuse® Bone Graft product during CW 5's tenure with the company, MEDTRONIC's sales representatives would participate in the surgeries by giving surgeons step-by-step instructions on the required procedures, even when the product was being used off-label. Moreover, CW 5 reported that off-label use of Infuse® Bone Graft was far more common than "on-label" use of the product, which was "few and far between."

166. According to CW 2, who was employed by MEDTRONIC as a product manager for MEDTRONIC's Biologics Marketing Department from 2005 to 2008 and specifically promoted sales of Infuse® Bone Graft during CW 2's tenure with the company, when doctors inquired about off-label use of Infuse® Bone Graft, MEDTRONIC sales representatives cited data from published literature and provided doctors with information regarding techniques for off-label procedures.

167. CW 3 also stated that MEDTRONIC held quarterly meetings in CW 3's sales region and that, periodically, a national Biologics specialist attended the quarterly meetings to explain how to conduct off-label applications of Infuse® Bone Graft.

2. MEDTRONIC's Use of Distributors to Promote Off-label Uses of Infuse®

168. Defendants also used distributors of Infuse® as a means of concealing the fraudulent payment which were made to physicians, clinics, and hospitals.

169. Beginning in 2004, distributors such as Benton Biomedical, Inc. (Scottsdale, AZ), Bio-Tek Medical (Memphis, TN), Rapp Medical Systems, Inc. (Indianapolis, IN), Medicraft Spinal Implants, Inc. (Atlanta, GA), Nu Med Technologies, Inc. (Tulsa, OK), Praxa Medical, Inc. (Glen Allen, VA), Surgical Systems, Inc. (Birmingham, AL), Spinal Associates, Ltd. (Mineola, NY), Rummer Medical, Inc. (Plano, TX), Medalliance, Inc. (Glenside, PA), Team Spine (St. Louis Park, MN), Team Spine Wisconsin (Brookfield, WI), First Choice Medical, Inc. (Nashville, TN), Carolina Spine Systems (Raleigh, NC), GHM, LLC (Houston, TX), and Mountain Medical Distributors (Anchorage, AK) began a program of giving expensive gifts to physicians.

170. The costs of these gifts totaled several hundreds of thousands of dollars per year. For example, MEDTRONIC SOFAMOR DANEK's distributors were given discretion to purchase medical texts and other items each worth several thousands of dollars and give it to a physician, physicians' group, or a hospital. After paying for these texts, the distributor would then send evidence of payment for the gift to MSD's accounting office. MSD would then charge the cost of the item to an account under the name of "Douglas King." An exhibit filed in the *Poteet* whistleblower action against MEDTRONIC demonstrates that the distributor would later be

reimbursed by MSD by increasing its next commission check in the amount equal to the cost of the gift.

D. MEDTRONIC Promoted Off-label Uses of Infuse® through its use of "Opinion Leaders" and Other Paid Physicians.

171. The MEDTRONIC Defendants engaged Opinion Leaders in a prolonged, wanton and malicious course of conduct to promote off-label use of Infuse® in violation of the FDCA with conscious and deliberate disregard of a serious risk to the health, safety, rights, and interest of Plaintiff and the general public, as described in this section.

172. Until recently, MEDTRONIC was very successful (and profitable) in driving off-label sales of Infuse® through undisclosed "consulting" and royalty agreements with physicians who, in exchange for handsome sums of money from MEDTRONIC or lavish trips paid for by MEDTRONIC, would push off-label usage in a number of ways, including by authoring or lending their names to scientific and medical literature that promoted such uses, as well as through direct advocacy to other spine surgeons.

173. MEDTRONIC actively promoted off-label use of Infuse® through its sales representatives and massive payments to its "Opinion Leader" spine surgeon consultants, which included sponsoring presentations at continuing medical education courses and appearances at consulting engagements promoting off-label applications of Infuse®. In turn, MEDTRONIC's sales force directed other physicians to these consultants and "Opinion Leaders" or to their written work (paid for and ghost-written by MEDTRONIC) to further drive off-label sales of Infuse®. Indeed, MEDTRONIC engaged in such conduct even after its settlement of the whistleblower action with the DOJ in which it agreed to employ stricter compliance controls regarding the sale and marketing of its spine products.

174. According to CW 1 in the *Minneapolis Firefighters* Complaint, who was employed by MEDTRONIC as a territory sales manager in the Southeast United States from 2002 through 2005, and who specifically promoted sales of the Infuse® Bone Graft product during CW 1's tenure with the company, MEDTRONIC "absolutely" promoted off-label use of Infuse® Bone Graft in a number of ways, including through MEDTRONIC-sponsored physician meetings. CW 1 explained that MEDTRONIC would set up a breakfast meeting or dinner in a particular area of the country and then have a number of local physicians attend for a presentation on off-label use of the product by a MEDTRONIC-paid physician consultant or "Key Opinion Leader," or "KOL," who was a surgeon selected by MEDTRONIC.

175. According to a whistleblower Complaint filed against MEDTRONIC in Boston, just days after Infuse® had been approved by the FDA solely for ALIF procedures, surgeons from Twin Cities Spine in Minneapolis, Minnesota invited former CEO Arthur Collins to view Infuse® being used in an off-label procedure. Other exhibits filed in that same whistleblower action include drafts of a consulting agreement between MEDTRONIC and Twin Cities Spine. The draft agreement proposed payments to several Twin Cities Spine surgeons of $4,000 per day, not to exceed a total of $80,000 per year for a total of $240,000 for the three-year contract term. The proposed contract also indicated that surgeons at Twin Cities Spine would receive 5% of net sales of "royalty products" sold in the U.S.

176. CW 13, who worked at MEDTRONIC from 1993 through 2005 primarily in the Northeastern region of the United States, stated that many of the methods used to promote Infuse® Bone Graft for off-label uses were part of a marketing plan originally developed during the product's launch. CW 13 stated that CW 13 was specifically brought over to MEDTRONIC SOFAMOR DANEK at the time of Infuse® Bone Graft's launch to help

develop a "referral marketing" campaign, which was designed to promote the product for off-label uses via a physician referral network. CW 13 stated that CW 13 helped identify which surgeons would be targeted as part of this campaign and what claims MEDTRONIC would make about the product, and also helped develop a "cookie-cutter" CD series that outlined the campaign and included information on off-label procedures that was distributed to MEDTRONIC sales representatives.

177. According to CW 13, the referral marketing program involved having surgeons meet with other surgeons as a means of prompting discussion of off-label uses of Infuse® Bone Graft among practitioners. CW 13 stated that MEDTRONIC also used a physician training program involving cadaver labs as a way of instructing surgeons on off-label applications.

178. According to CW 11, who was employed by MEDTRONIC as a spinal sales representative in the Northeast United States from 2002 to 2003 and specifically promoted sales of the Infuse® Bone Graft product during CW's 11 tenure with MEDTRONIC, "the way around" promoting Infuse® Bone Graft off-label was to bring doctors (including MEDTRONIC-paid consultants) using the product off-label to meetings or dinners with other doctors who would attend and be educated regarding off-label uses. CW 11 stated that while CW 11 was at MEDTRONIC, it was common knowledge within the company that most of the Infuse® Bone Graft sales were for off-label applications and that there was "no way" MEDTRONIC was achieving such high sales with on-label applications alone because the on-label applications were very narrow.

179. CW 1 stated that MEDTRONIC expected KOLs to use the company's products exclusively, write articles and give talks at such meetings to train other doctors. According to CW 1, another way MEDTRONIC promoted off-label use of Infuse® Bone Graft was by

bringing surgeons to Memphis for a "corporate visit" that included off-label training by guest surgeons or KOLs.

180. When CW 13 raised concerns about off-label promotion with supervisors— informing them that "we were clearly training these guys to use [Infuse® Bone Graft] in an off-label manner"—CW 13 was rebuffed. CW 13 stated that on several occasions, CW 13 was pulled aside by Vice President and Group Director of Sales for the Northeast Region, Joe Leroy, who told CW 13, **"We're paying you a lot of money to launch this. Shut your mouth and take the money. Let us worry about what is off-label or isn't."**

181. According to CW 13, the off-label promotion of Infuse® Bone Graft was "all done with a wink and a nod." Contrary to what senior management would say publicly, CW 13 said, the vice president-level managers would stress the sales quotas to sales representatives, which, according to CW 13, could not be met without having products sold for off-label uses.

182. MEDTRONIC was deeply involved in drafting, editing, and shaping the content of medical journal articles authored by Key Opinion Leaders, who received significant amounts of money through royalties and consulting fees from MEDTRONIC. MEDTRONIC's role was not disclosed in the published articles.

183. MEDTRONIC, Key Opinion Leaders, and other paid physicians formed financial agreements, which involved fraudulent promotion of off-label uses on Infuse® through a variety of means, outlined herein, for which Key Opinion Leaders were paid millions of dollars.

184. MEDTRONIC hosted VIP meetings, where many of its Key Opinion Leaders and other highly paid consultants would travel to Memphis at Defendants' expense to promote both on- and off-label uses of Infuse® and other MEDTRONIC SOFAMOR DANEK products to other

physicians, whose travel, food, beverage, and entertainment were also paid for by Defendants. These meetings occurred continuously and regularly.

185. MEDTRONIC paid a total of approximately $210 million to Key Opinion Leaders who authored studies on Infuse® between November 1996 and December 2010. These payments were classified by MEDTRONIC as royalties, consulting fees, and other miscellaneous arrangements.

186. When the FDA approved Infuse® in 2002 only for Anterior Lumbar Interbody Fusions, both MEDTRONIC and its Key Opinion Leaders knew they could not lawfully promote Infuse® for other uses in violation of FDA regulations.

187. In spite of this, MEDTRONIC continued to work with Key Opinion Leaders to encourage surgeons and hospitals (like Plaintiff's surgeon and hospital) to use Infuse® off-label.

188. At all times herein mentioned, Defendants failed to disclose the financial ties between MEDTRONIC and the Key Opinion Leaders in the publications of important medical studies that represented that Infuse® was safe and effective when used off-label, making it impossible for the medical community and Plaintiff's surgeon to make an informed decision about the published studies.

189. Plaintiff is informed and believes and based thereon alleges that in all of the principal studies cited in the Baucus-Grassley report released by the Senate Committee on Finance, MEDTRONIC officials inserted language into studies that promoted Infuse® as a better technique than harvesting bone from the patient's iliac crest by emphasizing the pain associated with using autograft, actively concealing adverse events and/or manipulating success criteria to falsely inflate the benefits of Infuse®. This was done in a number of ways:

a. In one of the original studies entitled "Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages," Dr. Haid, a Key Opinion Leader, and his co-authors caused adverse events to be underreported by requiring that an "event" be classified "unanticipated" in order for recognition as an "adverse event." In this study, the authors noted in the Study Progress section of the report, "[n]o unanticipated adverse device events have been reported…The reports of posterior bone formation are not considered unanticipated adverse device events since this was a possible adverse event listed in the risk analysis and informed consent form." Because heterotopic bone formation was then a recognized potential risk of rhBMP-2 use, redefinition of adverse event in such manner circumvented recognition of the hazard. A.R. Poynton & J.M. Lane, Safety profile for the clinical use of bone morphogenetic proteins in the spine, 27 Spine (16 Suppl 1) S40, 40-48. (2002).

b. Another means by which MEDTRONIC concealed adverse events in the medical literature was by classifying the event based on clinical consequence, rather than radiographic observation. Rodgers et al., 346 Brit. Med. J; 3981, 3985 (2013). "Medtronic confirmed that adverse events were classified on the basis or signs and symptoms, so potential adverse events such as heterotopic bone formation, osteolysis, and radiculitis not originally listed as adverse event categories in study protocols do not appear in summary tables in any internal reports." They suggested that any clinical consequence of such events may have been classified as "neurological" or as "back and/or leg pain." *Id.* Under

this methodology, adverse events were lumped into large and vague categories to mask the severity of what was occurring.

190. Additional, specific misrepresentations in the articles include the following:

a. Burkus JK, Gornet MF, Dickman CA, Zdeblick TA. Anterior lumbar interbody fusion using rhBMP–2 with tapered interbody cages. J. Spinal Disord. Tech. 2002; 15:337–49: "There were no unanticipated adverse events in either group." Yet, the executive summary includes information about adverse events resulting from local bone graft harvesting, but none regarding Infuse®-related adverse effects.

b. Burkus JK, Transfeldt EE, Kitchel SH, et al. Clinical and radiographic outcomes of anterior lumbar interbody fusion using recombinant human bone morphogenetic protein–2. Spine 2002: "In a clinical series of patients undergoing an ALIF procedure with a tapered cylindrical metal fusion cage, InFUSE™ Bone Graft has been shown to promote osteoinduction and increase rates of fusion" (citing article above). Furthermore, the authors stated, "[n]o unanticipated adverse events that were related to the use of InFUSE Bone Graft (rhBMP-2 and the collagen sponge carrier) occurred during the course of the study."

c. Burkus JK, Heim SE, Gornet MF, Zdeblick TA. Is INFUSE bone graft superior to autograft bone? An integrated analysis of clinical trials using the LT–CAGE lumbar tapered fusion device. J. Spinal Disord. Tech. 2003: "The probability of noninferiority of INFUSE Bone Graft to autograft was shown to be essentially 100%." This study also reported a 100% fusion rate for those patients receiving rhBMP-2.

d. Baskin DS, Ryan P, Sonntag V, et al. A prospective, randomized, controlled cervical fusion study using recombinant human bone morphogenetic protein–2 with the

CORNERSTONE–SR allograft ring and the ATLANTIS anterior cervical plate. Spine 2003:

i. "All the patients evaluated had solid fusions, 6, 12, and 24 months after surgery. There were no device-related adverse events…This pilot study demonstrates the feasibility of using rhBMP-2 safely and effectively in the cervical spine." (p. 1219) This study also reported a 100% fusion rate for those patients receiving rhBMP-2 and noted, "[t]he use of rhBMP-2 in anterior cervical fusion procedures eliminates the pain, scarring, and morbidity of iliac crest bone harvesting."

e. Burkus JK, Dorchak JD, Sanders DL. Radiographic assessment of interbody fusion using recombinant human bone morphogenetic protein type 2. Spine 2003: "High fusion rates associated with new bone formation inside and outside the cages can be achieved without harvesting bone from the iliac crest and without device-related adverse events."

f. Haid RW, Branch CL, Alexander JT, Burkus JK. Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages. Spine J. 2004: "No unanticipated device-related adverse events occurred."

g. Burkus JK, Sandhu HS, Gornet MF, Longley MC. Use of rhBMP–2 in combination with structural cortical allografts surgery: clinical and radiographic outcomes in anterior lumbar spinal fusion. J. Bone Joint Surg. Am. 2005; 87:1205–12: "The patients in the [rhBMP-2] group had significantly better outcomes than the control group with regard to the average length of surgery ($p < 0.001$), blood loss ($p < 0.001$), and hospital

stay ($p = 0.020$). Fusion rates were significantly better in the study group ($p < 0.001$)...In patients undergoing anterior lumbar interbody arthrodesis with threaded allograft cortical bone dowels, rhBMP-2/ACS was an effective replacement for autogeneous bone graft and eliminated the morbidity associated with graft harvesting."

h. Glassman SD, Dimar JR, Burkus K, et al. The efficacy of rhBMP–2 for posterolateral lumbar fusion in smokers. Spine 2007: This article reported a 100% fusion rate for non-smokers who received rhBMP-2 and a 95.2% fusion rate for smokers who received rhBMP-2, whereas non-smokers in the autograft group were reported to have a 94.15 fusion rate, and smokers were reported to have a 76.2% fusion rate."

i. Dimar JR, Glassman SD, Burkus JK, et al. Clinical and radiographic analysis of an optimized rhBMP–2 formulation as an autograft replacement in posterolateral lumbar spine arthrodesis. J. Bone Joint Surg. Am. 2009: "No adverse event that was specifically attributed to the use of rhBMP-2 metric in the study group was identified."

j. Burkus JK, Gornet MF. Six-Year Outcomes of Anterior Lumbar Interbody Arthrodesis with Use of Interbody Fusion Cages and Recombinant Human Bone Morphogenetic Protein–2. JBJS 2009: "In conclusion, the use of rhBMP-2 on an absorbable collagen sponge is an effective method of obtaining anterior intervertebral spinal fusion with use of a stand-alone interbody fusion device. In this long-term study, treatment with INFUSE Bone Graft and threaded titanium cages was shown to lead to high rates of fusion that were maintained at six years after surgery, and significant improvements in clinical outcome measures were maintained."

191. A more current example of underreporting and concealing adverse event data can be seen in the study titled, "Recombinant human bone morphogenetic protein-2 on an absorbable

collagen sponge with an osteoconductive bulking agent in posterolateral arthrodesis with instrumentation. A prospective randomized clinical trial." In this study, published in the *Journal and Bone and Joint Surgery* in 2009, the authors, who were also MEDTRONIC-paid consultants, under-reported "back and/or leg pain" by simply failing to acknowledge elevated rates of back and/or leg pain as an adverse event. Instead, the authors reported no adverse events associated with rhBMP-2. Id. When Dr. Eugene Carragee performed his analysis of documents provided to the FDA for this same study, however, the data revealed a three-fold increase in the number of back in leg pain adverse events as compared to the control group.

192. When reviewing a study authored by Dr. Haid, Dr. Burkus, and two others, reviewers from the *Spine Journal* commented, "The manuscript is full of biased statements that are a reflection of the data evaluators— the company that markets the product." Another reviewer said that "unless the authors can discuss the results in an unbiased manner, which they have been unable to do in its present form, this data should not be published."

193. The Key Opinion Leaders were assisted in writing and editing the thirteen principal medical journal articles by MEDTRONIC employees, acting within the scope of their employment. Many, if not most, of these employees worked for MEDTRONIC's marketing department.

194. The relators in a whistleblower Complaint filed against MEDTRONIC determined that the principal clinical investigators of BMP— Drs. Boden, Burkus, Haid, and Dorchak— for the period 1998 through 2004, collectively were awarded *41 patents* relating to MSD products. Prior to 1998, the approximate date of the inception of the Infuse® clinical, none of these physicians had invented or patented anything at all in the 61 years of their collective practice.

195. When describing the findings of the Senate report, Senator Baucus commented, "Medtronic's actions violate the trust patient have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has…Patients everywhere will be better served by a more open, honest system without this kind of collusion."

A. Dr. J Kenneth Burkus

196. Dr. Burkus was an author or co-author of each of the following published journal articles. All articles below were either edited or heavily drafted by MEDTRONIC employees:

a. Burkus JK, Gornet MF, Dickman CA, Zdeblick TA. Anterior lumbar interbody fusion using rhBMP–2 with tapered interbody cages. *J. Spinal Disord. Tech.* 2002; 15:337–49.

b. Burkus JK, Transfeldt EE, Kitchel SH, et al. Clinical and radiographic outcomes of anterior lumbar interbody fusion using recombinant human bone morphogenetic protein–2. *Spine* 2002.

c. Burkus JK, Heim SE, Gornet MF, Zdeblick TA. Is Infuse® bone graft superior to autograft bone? An integrated analysis of clinical trials using the LT–CAGE lumbar tapered fusion device. *J. Spinal Disord. Tech.* 2003.

d. Burkus JK, Dorchak JD, Sanders DL. Radiographic assessment of interbody fusion using recombinant human bone morphogenetic protein type 2. *Spine* 2003.

e. Haid RW, Branch CL, Alexander JT, Burkus JK. Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages. *Spine J.* 2004.

f. Burkus JK, Sandhu HS, Gornet MF, Longley MC. Use of rhBMP–2 in combination with structural cortical allografts surgery: clinical and radiographic outcomes in anterior lumbar spinal fusion. *J. Bone Joint Surg. Am.* 2005; 87:1205–12.

g. Glassman SD, Dimar JR, Burkus K, et al. The efficacy of rhBMP–2 for posterolateral lumbar fusion in smokers. *Spine* 2007.

h. Dimar JR, Glassman SD, Burkus JK, et al. Clinical and radiographic analysis of an optimized rhBMP–2 formulation as an autograft replacement in posterolateral lumbar spine arthrodesis. *J. Bone Joint Surg. Am.* 2009.

i. Burkus JK, Gornet MF. Six-Year Outcomes of Anterior Lumbar Interbody Arthrodesis with Use of Interbody Fusion Cages and Recombinant Human Bone Morphogenetic Protein–2. *JBJS* 2009.

j. Dawson E, Bae HW, Burkus JK, et al. Recombinant human bone morphogenetic protein–2 on an absorbable collagen sponge with an osteoconductive bulking agent in posterolateral arthrodesis with instrumentation. A prospective randomized trial. *J. Bone Joint Surg. Am.* 2009.

197. On July 20, 2001, Dr. Burkus e-mailed a draft of his study entitled, "Prospective Randomized Study of Radiographic Assessment of Interbody Fusion Using rhBMP-2" to Peter Wehrly, President of Biologics and US Sales at MEDTRONIC Sofamor Danek, and Bill Martin, Vice President of Spinal Marketing, Global Communications, and Medical Education for MEDTRONIC Spine & Biologics. In his e-mail, Dr. Burkus states, "I need some help with this paper. I have NOT completed any type of review of the data. I have no idea how to establish 'significance' and/or 'p' values."

198. On October 31, 2001, Dr. Burkus received an e-mail from Neil Beals, Vice President of Biologics Marketing for MEDTRONIC with the subject line, "Open LT Cage BMP Paper." The e-mail contains the following comment: "I think a bigger deal should be made of elimination of donor site pain with Infuse®…I would put that front and center in results, discussion and conclusion so that 'equivalent' results aren't received as a let down." Subsequent drafts of Dr. Burkus' study emphasized donor site pain associated with using allograft, an alternative to Infuse®.

199. On April 16, 2002, Dr. Burkus admitted that the co-authors to his study titled, "Clinical and Radiographic Outcomes of Anterior Lumbar Interbody Fusion Using Recombinant Human Bone Morphogenetic Protein-2," "did not write one word." Instead, Dr. Burkus' draft was reviewed multiple times by MEDTRONIC employees.

200. Another study authored chiefly by Dr. Kenneth Burkus, "Is Infuse® Bone Graft Superior to Autograft Bone? An Integrated Analysis of Clinical Trials Using the LT-CAGE Lumbar Tapered Fusion Device," was also edited by Rick Treharne of MEDTRONIC Sofamor Danek before it was submitted to the *Spine Journal* for publication.

201. On December 23, 2002, Peter Wehrly e-mailed Dr. Burkus's draft of the "PLIF Study Manuscript" to other MEDTRONIC employees, asking them to "champion this" by doing additional data analysis and editing. In commenting on the contents of the PLIF Study, Bill Martin, Vice President of Spinal Marketing for MEDTRONIC, commented that "I'm sure that none of us believe the PLIF technique is going to have a resurgence from this, but we may want to steer clear of calling it a flawed technique. There are still quite a few surgeons utilizing this technique and we probably don't want to put them in that position." MEDTRONIC employees continued to edit the PLIF Study until it was completed.

202. E-mails from October 10, 2007 demonstrate that Dr. Burkus collaborated with high-ranking MEDTRONIC employees on a study concerning the long-term effects of Infuse®.

203. In a published interview with SpineUniverse.com (last updated on December 10, 2009), Dr. Burkus said that he was "using rhBMP-2 in anterior and posterior lumbar spinal fusion surgeries" and that "no adverse events have been linked to the use of rhBMP-2."

204. Dr. Burkus and MEDTRONIC represented that various off-label uses of Infuse®, including use in PLIF and multi-level fusion procedures, were safe and superior to existing alternatives. These representations were made with the intent of inducing reliance of physicians throughout the country, including Plaintiff's surgeon.

205. Between May 2004 and December 2005, Dr. Burkus attended VIP meetings at MSD's Memphis headquarters on the following dates: July 30, 2004, August 13, 2004, September 23, 2004, January 10, 2005, February 7, 2005, March 7, 2005, April 4, 2005, April 28, 2005, June 13, 2005, October 7, 2005, and October 24, 2005.

206. Between 1996 and 2010, Dr. Burkus received $6,380,336.83 in royalties and consulting fees from MEDTRONIC.

207. E-mails between Dr. Burkus and a number of high-ranking MEDTRONIC employees, including Julie Bearcroft, indicate that MEDTRONIC was aware that Dr. Burkus' representations that Infuse® was both safe and superior to available alternatives were false.

B. Dr. Tom Zdeblick

208. Dr. Zdeblick was an author or co-author of each of the following published journal articles. Both articles below were either edited or heavily drafted by MEDTRONIC employees:

a. Burkus JK, Gornet MF, Dickman CA, Zdeblick TA. Anterior lumbar interbody fusion using rhBMP–2 with tapered interbody cages. *J. Spinal Disord. Tech.* 2002; 15:337–49.

b. Burkus JK, Heim SE, Gornet MF, Zdeblick TA. Is Infuse® bone graft superior to autograft bone? An integrated analysis of clinical trials using the LT–CAGE lumbar tapered fusion device. *J. Spinal Disord. Tech.* 2003.

209. On December 8, 2001, Neil Beals (who at the time served as the Group Director in the Biologics department of MEDTRONIC SOFAMOR DANEK and later as the Vice President of Biologics Marketing for MEDTRONIC) sent an e-mail to Bailey Lipscomb (a MEDTRONIC SOFAMOR DANEK employee), recounting a conversation he had with Dr. J Kenneth Burkus and Dr. Tom Zdeblick, wherein Dr. Zdeblick spoke of the Open LT Infuse® Manuscript draft as an opportunity to "focus on the message that is of interest to surgeons. Towards this, [Dr. Zdeblick] believes that we should be careful to define criteria for success and then report results of the study."

210. On December 20, 2001, Neil Beals e-mailed Bailey Lipscomb, asking for help in preparing a manuscript for Dr. Zdeblick.

211. MEDTRONIC collaborated with paid Key Opinion Leaders, including Dr. Zdeblick, to promote the off-label use of Infuse® Bone Graft by collaborating with employees of MEDTRONIC and MEDTRONIC SOFAMOR DANEK to draft and publish studies, emphasizing the safety and superiority of Infuse®.

212. One such article, co-authored by Dr. Zdeblick and two others, entitled "Is Infuse® Bone Graph Superior to Autograph Bone? An Integrated Analysis of Clinical Trials using the LT-CAGE Lumbar Tapered Fusion Device" was accepted for publication on December 19, 2002

and published in the *Journal of Spinal Disorders and Techniques'* second edition in 2003. Dr. Zdeblick was also the editor of this journal and failed to disclose his financial relationship with MEDTRONIC.

213. The article concluded, "We think that these analyses demonstrate the superiority of using Infuse® bone graft…with its superiority, Infuse® bone graft may now become the new gold standard for replacing autograft bone inside the LT-CAGE device when used with lumbar spinal fusions. Infuse® bone graft is now used exclusively for this purpose in our institutions."

214. In its 2003 Annual Report, MEDTRONIC cited to Dr. Zbeblick's article, indicating that Infuse® "…may become the 'new gold standard' in spinal fusion surgery." MEDTRONIC did not disclose its financial relationship with Dr. Zdeblick.

215. E-mails from October 10, 2007 demonstrate that Dr. Zdeblick collaborated with high-ranking MEDTRONIC employees on a study concerning the long-term effects of Infuse®.

216. Between May 2004 and December 2005, Dr. Zdeblick attended VIP meetings at MSD's Memphis headquarters on the following dates: May 17, 2004, August 20, 2004, November 15, 2004, and February 11, 2005. MEDTRONIC internal documents also indicate that Dr. Zdeblick was tentatively confirmed to attend VIP meetings on January 6, 2006 and May 8, 2006.

217. Between 1996 and 2010, Dr. Zdeblick received $34,168,739.81 in royalties and consulting fees from MEDTRONIC.

C. Dr. Scott D. Boden

218. Dr. Boden has written extensively on the use of Infuse® Bone Graft in off-label procedures. For example, Dr. Boden wrote that when used in situations slightly altered from its approved use, rhBMP-2 is likely to be effective. The article, published in *Orthopaedic Nursing*, also

praises the cost benefits of the product, noting that while rhBMP-2 "is quite expensive, [its] potential to lessen morbidity, accelerate healing, and provide more consistent results undoubtedly justify these costs in appropriately selected patients."

219. These findings were rebuffed by the 2013 YODA study, which found that at best, Infuse® is no better at fusing the spine or minimizing pain than autograft.

220. On August 16, 2004, Scott Boden dismissed concerns raised by the Co-Director of the Council on Socioeconomic Affairs for the North American Spine Society concerning the use of Infuse® in cervical fusion procedures. Although MEDTRONIC was aware of numerous adverse events associated with the off-label use of Infuse® in cervical fusions, Dr. Boden indicated that "it may be premature for any 'official' warning…"

221. Between May 2004 and December 2005, Dr. Boden attended VIP meetings at MSD's Memphis headquarters on the following dates: December 17, 2004, February 18, 2005, April 14, 2005, June 2-3, 2005, August 4-5, 2005, and October 26, 2005.

222. Between 1996 and 2010, Dr. Boden received $28,796,034.00 in royalties and consulting fees from MEDTRONIC.

D. Dr. Regis Haid

223. Dr. Regis Haid was a co-author of one of the principal studies published on Infuse®, as well as a co-author of numerous subsequent studies on the benefits of off-label uses of Infuse®. One article, entitled "Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cynlindrical interbody cages," published in the *Journal of Neurosurgery: Spine* in 2004, summarized the results of the disastrous 1999 PLIF study that had to be terminated due to the high incidence of adverse events in participants. However, rather than reporting the true findings of the experiment, Haid and his co-authors concluded,

"[T]his detailed, independent review of the results, which represents the first use of osteoinductive proteins in a PLIF procedure, are encouraging." Documents released by the U.S. Senate Committee on Finance demonstrate that this study was heavily drafted and edited by MEDTRONIC.

224. Editors of the *Spine Journal* commented that drafts of the article "should not be published in its current form. As noted by both Reviewer A and B, there is very little statistical significance differentiating the two groups [studied], but the authors and/or company sponsoring this study have attempted to use any possible positive trend to promote this technique."

225. Dr. Haid and MEDTRONIC intentionally represented that various off-label uses of Infuse®, including use in PLIF, TLIF, and cervical fusion procedures, were safe and superior to existing alternatives, and that these representations were made with the intent of inducing reliance of physicians throughout the country, including Plaintiff's surgeon.

226. Between May 2004 and December 2005, Dr. Haid attended VIP meetings at MSD's Memphis headquarters on the February 10, 2005 and November 18, 2005.

227. Between 1996 and 2010, Dr. Haid received $25,549,813.96 in royalties and consulting fees from MEDTRONIC. Of that amount, Dr. Haid received $2,484,450.94 in 2004.

E. Dr. Steven D. Glassman, Dr. John Dimar, III and the Leatherman Spine Center

228. According to CW 1 in the *Minneapolis Firefighters* Complaint, several surgeons from the Leatherman Spine Center would be asked to speak at MEDTRONIC-sponsored physician talks attended by between 10 and 25 surgeons, including several "pretty high profile" doctors. At these physician talks—which included a dinner attended by about 25 surgeons, another dinner with about 10 doctors, and a breakfast meeting attended by between 10 and 15 surgeons—a

MEDTRONIC consultant, such as one of the surgeons at the Leatherman Spine Center, would provide a presentation of off-label usage of Infuse® Bone Graft.

229. According to CW 1, "What [MEDTRONIC] would do is bring in one of their 'paid consultants' and set up a dinner in the area and invite a number of physicians to attend." The guest surgeon—the "paid consultant"—would then "basically give a presentation on off-label usage." Typically, "a canned presentation . . . was given, and the surgeon would talk about his experience with the product, and then there would be a Q&A at the end." According to CW 1, these physician talks were also attended by all MEDTRONIC sales representatives who worked in the area.

230. Dr. Steven Glassman and John Dimar, II were co-authors of each of the following published journal articles. Both articles below were either edited or heavily drafted by MEDTRONIC employees:

a. Glassman SD, Dimar JR, Burkus K, et al. The efficacy of rhBMP–2 for posterolateral lumbar fusion in smokers. *Spine* 2007.

b. Dimar JR, Glassman SD, Burkus JK, et al. Clinical and radiographic analysis of an optimized rhBMP–2 formulation as an autograft replacement in posterolateral lumbar spine arthrodesis. *J. Bone Joint Surg. Am.* 2009.

231. Dr. Steven Glassman collaborated with Julie Bearcroft, Director of Technology Management within Biologics for MEDTRONIC, on the first study. E-mails from September 2006 demonstrate that Julie Bearcroft edited Dr. Glassman's study on multiple occasions and that Dr. Glassman "incorporated most of [her] suggestions."

232. In the second article, Drs. Glassman, Dimar, and their co-authors began by stating, "There is mounting evidence supporting the efficacy of bone morphogenetic protein (BMP) for both

anterior interbody and posterolateral lumbar fusion." The articles concluded that those patients receiving BMP spent less on both surgical costs and follow-up treatment. However, this study only followed patients for three months after their surgeries.

233. Between May 2004 and December 2005, Dr. Glassman attended VIP meetings at MSD's Memphis headquarters on the following dates: May 11, 2004, January 27, 2005, March 10-11, 2005.

234. Between 1996 and 2010, Dr. Glassman received $1,748,263.36 in royalties and consulting fees from MEDTRONIC.

235. Between May 2004 and December 2005, Dr. Dimar attended VIP meetings at MSD's Memphis headquarters on January 27, 2005 and on March 10-11, 2005.

236. Between 1996 and 2010, Dr. Dimar received $1,766,366.21 in royalties and consulting fees from MEDTRONIC.

F. Dr. Timothy Kuklo

237. Documents obtained through a Freedom of Information Act (FOIA) request show that MEDTRONIC reimbursed Dr. Kuklo for a meeting with MEDTRONIC representatives in Memphis, Tennessee on April 20, 2004 regarding "Review of BMP Trauma and Spine Surgery." The meeting took place shortly before Dr. Kuklo and Dr. David Polly published an article in *Minnesota Medicine* pertaining to off-label uses of Infuse®.

238. On June 18, 2009, MEDTRONIC disclosed to the *Wall Street Journal* that Dr. Kuklo had received nearly $850,000 over the last ten years, most of which was paid between 2006 and 2009. Specifically, MEDTRONIC paid Dr. Kuklo $346,242 in 2007, the year in which Dr. Kuklo submitted his study on the effectiveness of Infuse® when used on soldiers' tibias.

MEDTRONIC also paid Dr. Kuklo $249,772 in 2008, the year Dr. Kuklo's study was published in the *Journal of Bone and Joint Surgery*.

239. A subsequent U.S. Army investigation revealed that Dr. Kuklo deliberately falsified data in Dr. Kuklo's 2008 study that exaggerated the benefits of off-label uses of Infuse® in in the tibia. Dr. Kuklo reported "strikingly" superior outcomes with Infuse® as compared to autograft.

240. Dr. Kuklo appeared as a "distinguished guest surgeon" at a MEDTRONIC Spine Division Business Overview Conference Call on September 28, 2006, alongside another MEDTRONIC consultant, Dr. Rick Sasso—who received $150,000 in consulting fees in 2006—as well as former MEDTRONIC CFO Gary L. Ellis and MEDTRONIC Spinal Division Senior Vice President Peter Wehrly ("Wehrly"). During the call, a Merrill Lynch analyst asked about "issues that have come up in the past in terms of potential side effects with using Infuse® in the cervical region," and whether it was a concern for surgeons. Dr. Sasso responded by referring to a "Level 1, controlled randomized study which was published in 2002" which, according to Dr. Sasso, demonstrated that "when you used the appropriate dosage of Infuse®, you did not get problems with esophageal obstruction and problems swallowing." Wehrly then asked whether Dr. Kuklo had anything to add, and Dr. Kuklo responded that the question "was well answered as far as appropriate dosage. I think it's really the bottom line."

241. Dr. Kuklo collaborated with two other physicians at Washington University, Dr. Lawrence G. Lenke and Dr. Keith H. Bridewell. Both Dr. Lenke and Dr. Bridewell served as guest surgeons during corporate visits, in which MEDTRONIC would invite targeted surgeons to attend training sessions in Memphis, Tennessee. While in Memphis, the visiting surgeons would meet with MEDTRONIC corporate officers, product managers, and guest surgeons,

such as Drs. Lenke and Bridwell. The visiting surgeons also received "hands-on training" on Infuse® Bone Graft, including instruction in cadaver labs. According to CW 1 in the *Minneapolis Firefighters* Complaint, who personally attended two such meetings, "There was training on off-label procedures, for sure." The visiting surgeons "would bring up the use of Infuse® and ask how to use it, and [the guest surgeons] would show them how to do it." CW 1 further stated that MEDTRONIC chose which surgeons to invite to these corporate visits based in part upon the volume of Infuse® Bone Graft procedures they performed.

242. In July 2009, Senator Grassley disclosed information demonstrating that Dr. Kuklo hid his financial relationship from Washington University and failed to disclose his financial ties in conflict of interest disclosure forms while he continued to conduct research on Infuse®.

G. Dr. David Polly

243. Although Dr. Polly has claimed that his consulting relationship with MEDTRONIC did not begin until 2004, MEDTRONIC paid nearly $30,000 in travel expenses to Dr. Polly for speeches he gave at a variety of medical conferences in the Bahamas, San Diego, and a $10,000 trip to Switzerland, while Dr. Polly was employed at Walter Reed Medical Center in 2003.

244. At the above-mentioned conferences, Dr. Polly presented his research, which allegedly demonstrated that Infuse® was more cost effective than other spinal products.

245. While he was on active duty at Walter Reed, Dr. Polly published the first cost-benefit analysis of Infuse® in October 2003 in *Orthopedics* magazine. Dr. Burkus was also a co-author. Dr. Polly stated that this study was conducted as "part of his official duties in the U.S. Army."

246. The Relator in a whistleblower action, *Poteet*, filed against MEDTRONIC and a number of their paid physicians, personally booked both domestic and international flights for Dr. Polly on behalf of MEDTRONIC SOFAMOR DANEK USA, INC.

247. In November 2003, within a month after leaving military service, Dr. Polly joined an orthopedic group in Minneapolis that included other highly paid "consultants" for Defendants.

248. Information released by Senator Grassley, which contained billing reports from MEDTRONIC, indicates that between 2003 and 2007, Dr. Polly attended numerous meetings with senior MEDTRONIC executives, including former CEO William Hawkins, former COO Michael DeMane, and former President of MEDTRONIC Spinal and Biologics, Peter Wehrly. For example, records show meetings and other contacts between Dr. Polly and William Hawkins on the following dates: February 13, 2007, June 15, 2007, July 27, 2007, August 8, 2007, August 24, 2007, September 26, 2007, and September 27, 2007. The records also show that one meeting on July 13, 2005 took place in order to discuss a "spine surgery advocacy effort."

249. In September 2008, Senator Grassley requested the names of consulting physicians paid by MEDTRONIC. MEDTRONIC failed to disclose Dr. Polly's name in its response to Senator Grassley.

250. Between May 2004 and December 2005, Dr. Polly attended VIP meetings at MSD's Memphis headquarters on the following dates: July 27, 2004, August 12, 2004, January 5, 2005, March 18, 2005, June 30, 2005, June 30, 2005, and September 20, 2005.

251. Between 2003 and 2007, Dr. Polly received $1,140,000 in royalties and consulting fees from MEDTRONIC.

E. MEDTRONIC Promoted Off-label Uses of Infuse® through False Statements Published in Medical Literature

252. From at least 2001 until the summer of 2006, MEDTRONIC engaged in an active ghostwriting program of the articles and study reports in order to suppress any information about the real risks and dangers posed by the off-label uses of Infuse® Bone Graft. The specific misrepresentations regarding the products' safety and efficacy include: (1) the active concealment of adverse events; (2) the deliberate omission of related risks, including but not limited to, dangerous bone growth, inflammatory reactions, osteolysis, and an over-emphasis on the problems posed by traditional bone graft procedures, such as autograft; (3) dosing requirements for patients, such that doctors were misled as to how much rhBMP-2 to use and what amount of bone growth would result. The effect of these misrepresentations was that it was nearly impossible for a physician to understand the real risks associated with using Infuse® off-label.

253. MEDTRONIC, while providing spine surgeons with MEDTRONIC-funded studies and published articles purporting to support the efficacy and safety of the off-label uses, simultaneously and systematically concealed or downplayed other non-MEDTRONIC-funded studies and articles demonstrating serious and frequent adverse events caused by the same off-label uses.

1. The June 2011 Edition of The Spine Journal

254. On June 1, 2011, *The Spine Journal*, a leading medical journal in the United States, published a special edition dedicated to addressing serious patient safety and ethical concerns related to the use of rhBMP-2 (Infuse®) in the spine.

255. This special edition reviewed thirteen peer-reviewed articles (written by MEDTRONIC and its paid physicians) about rhBMP-2 and concluded that these articles had inaccurately reported the safety of rhBMP-2 applications in the spine by underestimating its risks.

256. In an editorial summarizing the findings of this special issue, five prominent physicians, industry-sponsored trials and reports were "remarkable for the complete absence of reported rhBMP-2 related clinical adverse events." For example, the industry-sponsored articles omitted mention of indications from the earliest trials of inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation, urinary retention, bone resorption, and implant displacement. They also omitted mention of sterility and cancer risks associated with rhBMP2, as reported in FDA documents and hearings. The trials and reports suffered from idiosyncratic trial design, reporting bias, and peer review/publication shortfalls.

257. According to this editorial and several of the accompanying articles, the thirteen MEDTRONIC-funded articles reported only successful fusions and extremely low or nonexistent rates of complications with Infuse®, which led to the growth of off-label uses of Infuse® in lumbar and cervical fusion procedures. According to the authors in *The Spine Journal*, the MEDTRONIC-funded articles "may have promoted widespread poorly considered on- and off-label use, eventual life-threatening complications and deaths."

258. Contrary to the conclusions of the earlier MEDTRONIC-sponsored trials and articles, an article in this special issue of *The Spine Journal* suggested "an estimate of adverse events associated with rhBMP-2 use in spine fusion ranging from 10% to 50% depending on approach."

> Anterior cervical fusion with rhBMP-2 has an estimated 40% greater risk of adverse events with rBMP-2 in the early postoperative period, including life-threatening events. After anterior interbody lumbar fusion rates of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation were higher

> after using rhBMP-2 than controls. Posterior lumbar interbody fusion was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes. In posterolateral fusions, the risk of adverse effects associated with rhBMP-2 use was equivalent to or greater than that of iliac crest bone graft harvesting, and 15% to 20% of subjects reported early back pain and leg pain adverse events; higher doses of rhBMP-2 were also associated with a greater apparent risk of new malignancy.

Eugene Carragee, Eric L. Hurwitz & Bradley K. Weiner, *A Critical Review of Recombinant GHuman Bone Morphogenetic Protein-2 Trials in Spinal Surgery: Emerging Safety Controls and Lessons Learned, The Spine Journal* 11, 471-72 (2011).

259. The following are some of the other significant conclusions in these articles in the June 1, 2011 issue of *The Spine Journal*:

a. Many of the risks now accepted have been known since a publication by Poynton and Lane in 2002, which listed overgrown and uncontrolled bone formation, osteoclast activity (graft subsidence, migration, loss of fixation, etc.), local safety (inflammation, edema, wound problems, and infection), potential negative effect of BMPs on exposed dura and nerves (neurological events, retrograde ejaculation, persistent bladder retention, early back pain, leg pain, radiculitis, functional loss, carcinogenicity). *However, it appears that these risks were ultimately washed out and marginalized by the wealth of positive data from industry-sponsored studies.*

b. A 2-year rhBMP-2 follow-up published by Burkus, et al., reported no adverse events. However, in a 6-year follow-up publication using the same subjects, the authors contradict their earlier publication stating that there had been seven early adverse events associated with subsidence in the hBMP-2 group, yet they were not reported in the two-year follow-up.

c. In fact, on closer inspection of the Burkus studies, it was noted that all adverse events mentioned in the six-year follow-up had occurred within the first two years.

d. Furthermore, four of the adverse events required further surgery, and 22 additional surgeries for device failures occurred in the same rhBMP-2 group between 0-2 years after surgery according to the FDA summary, but were not specifically reported in the 2003 or 2004 studies, which were the same patients over the same time frame.

e. The estimates of rhBMP-2 safety from the original publications underestimated the rhBMP-2-related adverse events of the product. In the small pilot studies, there were inadequate numbers to assess safety, but some suggestion of potential harm was seen in at least one study. In the larger trials, there is evidence in each trial that rhBMP-2 complications may be common and may be serious, but in each publication these were underreported.

f. The presence and magnitude of conflicts of interest and the potential for reporting bias were either not reported or were unclear in each of the original industry-sponsored studies. Some of the conflicts of interest statements reported appeared to be vague, unintelligible, or were internally inconsistent.

g. The original estimates of ICBG (iliac crest bone graft, the pre-rhBMP-2 gold standard procedure for spinal fusion) harvesting morbidity were based upon invalid assumptions and methodology. This in turn may have exaggerated the benefit or underestimated the morbidity of rhBMP-2 in the clinical situations tested.

h. The control group methods and techniques, as selected for both posterior approach methods (PLIF and PLF), were potentially handicapped by significant design bias against the controls.

i. In those studies for which other data sources have been made available on the same patient sets (either FDA documents or subsequent reporting of follow-up data), serious contradictory findings have emerged. Major complications, additional surgeries, neurologic/urologic injury, and other major back/leg pain events were apparently observed but not reported in the original articles.

j. By reporting perfect or near perfect safety, the original studies might have led others to widespread off-label use of the product with some potentially catastrophic outcomes. Revised estimates of adverse events are:

i. Posterior Lumbar Interbody Fusion Techniques: 25-50% risk of associated adverse events.

ii. Anterior Lumbar Interbody Fusion Techniques: 10-15% risk of adverse events.

iii. Anterior Cervical Fusion: 40% greater risk of adverse events in the acute postoperative period, including potentially life-threatening complications.

iv. Posterolateral fusions: equivalent or greater early postoperative risk of morbidity compared with ICBG harvesting for this dosage; 16-20% of rhBMP-2 subjects had adverse back and leg pain events, *a probable two to threefold increase in the first three months after surgery over control groups* (emphasis added).

260. A more recent study, CL Adams, K Ogden, IK Robertson, S Brodhurst, & D Edis, *The effectiveness and safety of recombinant bone morphogenetic protein-2 versus local bone graft in primary lumbar interbody fusion, The Spine Journal,* 39(2):164-71 (2014), concluded that patients who underwent a transforaminal or posterior lumber interbody fusion using rhBMP-2

were "4.66 times more likely to have a post-operative complication" than a patient undergoing either of those procedures with local bone graft.

261. MEDTRONIC's current CEO, Omar Ishrak, responded to the *Spine Journal*'s criticism, stating, "While the spine journal articles raise questions about researchers' conclusions in their peer-reviewed literature, the articles do not raise questions about the data MEDTRONIC submitted to the FDA in the approval process or the information available to the physicians today through the instructions-for-use brochure attached to each product sold."

262. The *Milwaukee Journal Sentinel* reported on additional responses by MEDTRONIC executives:

> *In an interview Tuesday with* Journal Sentinel, *MEDTRONIC officials said they are now looking into the issue of whether published articles failed to properly report various complications linked to Infuse®. 'We are very serious about this,' said Richard Kuntz, MEDTRONIC's Senior Vice President and Chief Scientific, Clinical and Regulatory Officer. 'We will do a full analysis of these papers.' Kuntz and Christopher O'Connell, an executive vice president who oversees the MEDTRONIC Division that includes Infuse®, also said they will provide a full screening of royalties and other payments to doctors who authored Infuse® papers.*

2. The YODA Study Fails to Find Any Clinical Indications for Infuse®

263. In response to the contents of the June 2011 issue of the *Spine Journal*, MEDTRONIC provided a grant to Yale University in August 2011 to conduct independent reviews of the safety and effectiveness of Infuse®. This review took place through the Yale University Open Data Access Project (YODA).

264. MEDTRONIC's current CEO, Omar Ishrak, spoke about MEDTRONIC's decision to provide the grant to Yale: "Integrity and patient safety are MEDTRONIC's highest priorities, so it is important that a respected academic institution provide a publicly trusted source of information by way of these systematic reviews and the novel data access program for researchers."

265. Yale University commissioned two research teams, one at the University of York in England and another at Oregon Health & Science University to conduct the independent studies. Both addressed the same question: *Does BMP-2 safely improve outcomes of spinal fusion surgery compared with the "gold standard" of iliac crest bone grafting?*

266. The results of these studies, published in the June 18, 2013 issue of *Annals of Internal Medicine,* answered the question above with a resounding "No."

267. "After systematic evaluation of all available evidence, both systematic reviews published here independently conclude that rhBMP-2, compared with iliac crest bone grafting, does not improve pain or function, and increases adverse events, possible including cancer," noted Christine Laine, MD, editor-in-chief of *Annals of Internal Medicine,* in an editorial accompanying the YODA reports.

268. The review conducted by the University of York concluded, "At 24 months, rhBMP-2 increases fusion rates, reduces pain *by a clinically insignificant amount*, and increases early postsurgical pain compared with [iliac cresting bone graft]" (emphasis added). The reviewers also commented on their review of reported adverse events: "Given the heterogeneity of these studies and their potential for bias, we did not meta-analyze these data. Despite the methodological issues, we found evidence suggestive of higher rates of particular adverse events among rhBMP-2 recipients."

269. The review conducted by Oregon Health & Science University determined, "In spinal fusion, *rhBMP-2 has no proven clinical advantage over bone graft and may be associated with important harms,* making it difficult to identify clear indications for rhBMP-2. Earlier disclosure of all relevant data would have better informed clinicians and the public than the initial published trial reports did" (emphasis added).

270. According to Dr. Rongwei Fu and his colleagues at Oregon Health & Sciences University, "Based on our analysis, it is difficult for us to find a clear indication to use rhBMP-2 for spinal fusion surgery."

271. A subsequent article published in the August 2013 edition of *The Back Letter* commented that the MEDTRONIC-sponsored clinical trials "denied patients and their physicians the ability to make informed decisions about a key component of fusion surgery for almost a decade. False perceptions about the safety of BMP-2 led to a rash of serious injuries and other adverse events. And in an era of spiraling costs, misinformation about BMP-2 denied payers and healthcare systems the opportunity to underwrite the most cost-effective care options."

272. According to Dr. Charles A. Mick, president of the North American Spine Society, "While this transparency is laudable, it is overdue. Neither the original investigators nor industry were exonerated by this repeated data scrutiny, which led to conclusions quite disparate from those in many published studies on their rhBMP-2 product… Open access data and post-marketing analysis can never be a substitute for accurate, ethical and unbiased research in the first place."

273. Dr. Eugene Carragee also weighed in on the YODA findings: "A surgeon would need a truly exceptional case to use BMP-2 when the data supporting its use are marginal and the scant complications data we have comes through potentially biased filters at every level. If the complications monitoring process were as biased as the analyses and reporting processes have proven to be, then [the] data YODA was given fundamentally and systematically misrepresent the risk of BMP-2 use."

F. MEDTRONIC Set Aggressive and Impossible Sales Goals for Infuse®

274. CW 3 stated that Infuse® Bone Graft was "tremendous" to MEDTRONIC's overall sales growth.

275. CW 1 reported that MEDTRONIC created sales quotas for Infuse® Bone Graft that were much higher than could possibly be reached with only FDA-approved indications of the product and that "there was no way" that MEDTRONIC executives could have expected the sales quotas to be met without off-label sales.

276. CW 2 confirmed that MEDTRONIC set very high sales targets with sales expected to grow 15-20% year-over year and that MEDTRONIC's Spine (and mainly) Biologics division was considered "one of the big growth engines of MEDTRONIC." This statement was also corroborated by CW 9.

277. According to CW 9, who was employed by MEDTRONIC as a Spinal sales representative in the Southwest United States from 2004 through 2008 and specifically promoted sales of Infuse® Bone Graft during CW 9's tenure with the company, the vast majority of Infuse® Bone Graft surgeries were off-label applications of the product because very few surgeons were using the LT-CAGE or ALIF procedure. CW 9 further stated that the PLIF and TLIF off-label procedures were far more common surgeries than ALIF surgery in the lumbar region.

278. CW 6, who was employed by MEDTRONIC from 2000 through 2007 including as a clinical data director and involved with the promotion of Infuse® Bone Graft, further reported that with regard to off-label cervical applications of the product, the then-packaged dosage of rhBMP-2 was far too large for the cervical spine and MEDTRONIC's marketing department advised doctors using the product in the cervical spine that they would have to throw away a big portion or half of the rhBMP-2 dosage and that "more is not better" in the cervical spine.

G. MEDTRONIC Began Selling Infuse® Kits in Various Sizes to Accommodate a Variety of Off-label Uses

279. According to CW 7, who was employed by MEDTRONIC as a Spinal sales representative in the Northwest United States from 1998 until 2003 and specifically promoted sales of the Infuse® Bone Graft product during CW 7's tenure with the company, when CW 7 was at MEDTRONIC, CW 7 received a small booklet the size of an address book that was about five pages long and contained information regarding the volume or dosage of rhBMP-2 that should be used for off-label applications of Infuse® Bone Graft. CW 7 knows the book was prepared by MEDTRONIC because CW 7 received it from the company, but stated that MEDTRONIC's name could not be found anywhere in the book. CW 7 stated that if a doctor inquired about off-label use of the product, MEDTRONIC employees would state what they know about other surgeons using the product off-label. CW 7 further stated that during CW 7's tenure with MEDTRONIC, Infuse® Bone Graft kits were too large to fully use in the cervical spine and that today MEDTRONIC markets smaller sizes of Infuse® Bone Graft and that doing so does not make sense if the product is intended to be limited to FDA-approved usage.

280. CW 4, who was employed by MEDTRONIC as a spinal sales representative in the Northeast United States from 2002 through 2006 and specifically promoted sales of INFUSE Bone Graft during CW 4's tenure with MEDTRONIC, reported that when surgeons first began to use Infuse® Bone Graft in cervical fusion surgery they were not aware of the potential adverse consequences of using an entire sponge (or full rhBMP-2 dosage) in the cervical spine, but after MEDTRONIC's national sales meetings, word would spread throughout the medical community regarding how to use Infuse® Bone Graft in the cervical spine although the product was only FDA-approved for lumbar anterior fusion.

281. CW 5 further reported that when adverse reactions were being reported with cervical applications of Infuse® Bone Graft in the first part of 2006, MEDTRONIC organized a

conference call with its sales representatives to instruct them that surgeons should not be using the "whole sponge" (or full rhBMP-2 dosage) in cervical fusion surgery, which was an off-label, non-FDA approved use of Infuse® Bone Graft.

282. On July 1, 2008, the FDA issued a Public Health Notification, advising physicians oh "life-threatening complications associated with recombinant human Bone Morphogenetic Protein (rhBMP) when used in the cervical spine."

283. Rather than admitting that cervical uses of Infuse® were both off-label and dangerous, MEDTRONIC represented that the problem was instead an issue related to dosing. In a MEDTRONIC press release dated July 23, 2008 (only days after the FDA warning about the severe adverse events associated with cervical uses of Infuse®), MEDTRONIC announced the release of Infuse® kits which were "Now in Smaller Sizes!" The press release failed to cite a new procedure for which the smaller kits were indicated. Instead, MEDTRONIC suggested that surgeons may have a wider array of choice when choosing the amount of rhBMP-2 to use, or that the smaller kits might simply "serve as a backup when one cage or sponge is dropped or contaminated prior to implantation…" According to CW 4 and CW 7, these smaller kits were designed to increase off-label uses of Infuse® in cervical applications.

VII. NEW DATA AND ARTICLES BEGIN TO EXPOSE MEDTRONIC'S FRAUDULENT SCHEME

A. MEDTRONIC Settles Whistleblower Litigation with the DOJ and Agrees to Enter into a Corporate Integrity Agreement

284. MEDTRONIC was named as a defendant in two *qui tam* actions, *United States ex. Rel. (UNDER SEAL) v. MEDTRONIC, Inc., et al.*, Civil Action No. 02-2709 (W.D. Tenn. 2002) (hereinafter *"[Under Seal]"*), and *United States ex rel. Poteet v. MEDTRONIC, Inc. et al.*,

Civil Action no. 03-2979 (W.D. Tenn. 2003) (hereinafter *"Poteet I"*) (collectively the "qui tam lawsuits"). Both lawsuits alleged that MEDTRONIC violated the False Claims Act, 31 U.S.C. § 3729, *et seq*., by paying illegal kickbacks to physicians in connection with promoting the off-label use of Infuse® in the spine, which resulted in the submission of false or fraudulent claims to federal health care programs.

285. Based on its investigation, the DOJ contended that certain of the payments, services, and remuneration mentioned above were improper and resulted in the submission of false or fraudulent claims in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), *et seq.*, which prohibits individuals from offering soliciting or making any payment or remuneration to induce businesses that are reimbursed under a federal or state health care program, and the False Claims Act, 31 U.S.C. § 3729, *et seq.*, which provides penalties for the submission of false claims to the federal government. Both *[Under Seal]* and *Poteet I* were brought by MEDTRONIC's former employees who made these allegations.

286. In these lawsuits, the DOJ contended that between January 1, 1998 and April 30, 2003, MEDTRONIC made payments and provided other remuneration to a number of physicians and entities in connection with its spinal products in the form of (1) payments and other remuneration for physicians' attendance and expenses at medical education events, "think tanks," VIP/opinion leader events, and meetings at resort locations; (2) services and payments for services to physicians though MEDTRONIC's Healthcare Economic Services and eBusiness Departments; and (3) payments made pursuant to consulting, royalty, fellowship and research agreements with various physicians and entities.

287. Specifically, *[Under Seal]*, was brought by a former MEDTONIC in-house counsel, who alleged that MEDTRONIC's aggressive and illegal sales and marketing efforts were intended

by MEDTRONIC to improperly induce physicians to use MEDTRONIC's spinal products, including Infuse®. The conduct alleged included, *inter alia*: (1) lucrative consulting and royalty agreements with physicians that used MEDTRONIC Spine products, "the true purpose [of which were] to funnel money to the physicians so that they will be induced to use [MEDTRONIC Spinal] products;" and (2) "[l]avish all-expense paid trips to fine resorts…disguised as Medical Education seminars, think tanks, or discussion groups…held in places such as Hawaii, Cancun, Alaska, Beaver Creek, Whistler, Malaysia, Amelia Island, Teton Valley, and New Orleans at Mardi Gras…[t]he purpose of these lavish trips was to induce the physicians to use [MEDTRONIC Spinal] products."

288. The complaint further alleged that: "Most of the illegal kickback practices described herein were begun by Sofamor Danek and continued by [MEDTRONIC] after the acquisition. Kickbacks were the culture and way of doing business at Sofamor Danek and the company was determined to continue that culture, and did continue that culture, when Sofamor Danek became part of the MEDTRONIC empire."

289. *Poteet I* was brought by a formed MEDTRONIC employee who was tasked by MEDTRONIC to arrange travel (including expense reimbursement) for numerous spinal surgeons to attend MEDTRONIC-sponsored events and other professional meetings. This former employee also alleged that MEDTRONIC paid surgeons substantial fees— sometimes up to hundreds of thousands of dollars per year — for consulting services that were grossly in excess of their fair market value, entered into royalty agreements that were designed to disguise illegal remuneration, and provided physicians opportunities for lavish travel and recreational activities such as "golf, snorkeling, sailing, fishing, shopping trips, [and] horse-back riding" for using MEDTRONIC products. These consulting agreements and other payments were

illegitimate means of inducing physicians to use MEDTONIC products and to recommend to other physicians that they do the same.

290. On July 18, 2006, MEDTRONIC agreed to pay $40 million to the United States of America to settle these lawsuits under the False Claims Act, 31 U.S.C. §§ 3729-3733, the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, and the Program Fund Civil Remedies Act, 31 U.S.C. §§ 3801-12.

291. As part of the DOJ settlement, MEDTRONIC agreed to enter into a five-year Corporate Integrity Agreement ("CIA") with the Office of the Inspector General/Health and Human Services that, as MEDTRONIC described in its July 18, 2006 press release, implemented substantial oversight structures and procedures meant to ensure "top-level attention to corporate compliance measures." Among other things, the CIA required MEDTRONIC to establish an electronic database to capture and manage all non-sales related transactions between MEDTRONIC's Spinal segment and its physicians or customers, with all such transactions subject to an established set of internal controls and review processes, including monitoring by MEDTRONIC senior management and MEDTRONIC's Chief Compliance Officer.

292. Moreover, the CIA required MEDTRONIC to implement internal policies and procedures to ensure stricter regulatory compliance, which obligated MEDTRONIC to institute a number of changes to improve oversight of its Spinal division.

293. Significantly, the CIA also required MEDTRONIC to adopt procedures to ensure that any "arrangements"—a term intended to cover physicians consulting agreements and broadly defined as engagements involving "directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; [] between [MEDTRONIC] and any actual or potential source of

health care business [i.e., physicians]"— would not violate federal law. Such procedures were to include, among other things: (1) creating a database of all existing and new or renewed arrangements; (2) tracking remuneration from MEDTRONIC to all other parties to such arrangements; (3) tracking service and activity logs to ensure that parties to an arrangement are performing their duties under the applicable arrangement; (4) implementing procedures that ensure all arrangements are reviewed for adherence to the Anti-Kickback Statute; and (5) regular (at least quarterly) review by the MEDTRONIC Compliance Officer of the arrangements database along with reporting (at least quarterly) to the MEDTRONIC Compliance Committee.

294. The CIA and the previous whistleblower and wrongful termination litigation placed MEDTRONIC and its agents on actual notice of its practice of marketing and promoting Infuse® for off-label uses was improper and required wholesale change to avoid further adverse regulatory action or other liability.

295. As a result of this settlement, MEDTRONIC agreed to negotiate with representatives of the National Association of Medicaid Fraud Control Units to reach an agreement that provides for distribution of certain sums to the several states with which MEDTRONIC agreed to a settlement concerning the conduct at issue in the False Claims lawsuits.

296. Nonetheless, MEDTRONIC's unlawful practices continued, as did MEDTRONIC's aggressive efforts to drive Infuse® sales by promoting off-label applications, such as the type used on the Plaintiff. MEDTRONIC has continued to improperly and illegally promote the off-label use of Infuse® for non-FDA-approved uses of the product. Indeed, they were motivated to do so knowing that absent off-label use, sales of Infuse® would dramatically decline. In order to obviate a decline in sales revenue, MEDTRONIC continued to covertly

employ the same lucrative "consulting" arrangements and other unlawful conduct to promote off-label uses of Infuse®.

297. As a result of MEDTRONIC's undisclosed misconduct, the percentage of off-label usage increased over time, including after the DOJ settlement on July 14, 2006. By 2011, off-label use of Infuse® constituted more than 90% of the total use of Infuse® in spinal fusion procedures.

298. Indeed, MEDTRONIC's unlawful marketing and promotion was so effective that a MEDTRONIC analyst from Bernstein Research noted in a November 21, 2006 report that analysts were "expecting *continued indication expansion (e.g., recent dental approval and likely approval for posterior lateral fusion) for Infuse® to be the main driver for the spinal business* in the mid-term." (Emphasis added.) What this analyst and the public at large did not know was that, despite the limited FDA-approved applications of Infuse®, MEDTRONIC continued to drive sales solely through off-label indications. MEDTRONIC persisted in doing so despite the CIA, the material risk of further regulatory action or other liability, and in conscious disregard of the health and welfare of spine patients such as the Plaintiff.

ROBERT SKOUBO'S SURGERY

299. On July 21, 2010, Plaintiff ROBERT SKOUBO underwent a transforaminal lumbar interbody fusion at L4-5 in Oregon. To achieve fusion, Plaintiff's surgeon performed an off-label procedure by utilizing a transforaminal approach, as well as by failing to use the required LT-Cage™.

300. The MEDTRONIC Defendants, through their sales representatives and paid Key Opinion Leaders, directly and indirectly promoted, trained, and encouraged Plaintiff's surgeon to

engage in the off-label procedure of utilizing a transforaminal approach without the required LT-Cages™.

301. In or around 2010, Plaintiff was diagnosed with ectopic bone growth and neuritis. As a result, Plaintiff has required extensive medical treatment.

302. As a result of the off-label use and failure to warn of off-label use of Infuse® as designed, manufactured, sold, supplied, and distributed by MEDTRONIC, and as a result of the negligence, callousness, and the other wrongdoing and misconduct of MEDTRONIC as described herein:

a. Plaintiff ROBERT SKOUBO has been injured and suffers injuries to his body and mind, the exact nature of which is not completely known to date.

b. Plaintiff ROBERT SKOUBO has sustained economic losses, including loss of earnings and diminution of his earning capacity, the exact amount of which is presently unknown.

c. Plaintiff ROBERT SKOUBO will be required to incur additional medical expenses in the future as a result of the injury and damages he has suffered.

303. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

304. Defendant's conduct as alleged above was malicious, intentional, and outrageous and constitutes a willful and wanton disregard to the rights and safety of others. Such conduct was directed specifically at Plaintiff and as such, warrants an imposition of punitive damages.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
Fraudulent Misrepresentation and Fraud in the Inducement

305. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

306. In connection with their Infuse® products, the MEDTRONIC Defendants fraudulently and intentionally misrepresented material and important health and safety product information to Plaintiff and Plaintiff's physicians, all as alleged in this Complaint. Plaintiff and Plaintiff's physicians would not have decided to use Infuse® without an LT-Cage™ or to implant it via a transforaminal approach, without the LT-Cage™ had they known of the safety risks related to Infuse®.

307. MEDTRONIC marketed their Infuse® product to and for the benefit of Plaintiff, and marketed it to Plaintiff's physicians, and Defendants knew or had reason to know that Plaintiff and Plaintiff's physicians would use the product.

308. Any of the following is sufficient to independently establish the MEDTRONIC Defendants' liability for fraudulent misrepresentation and/or fraud in the inducement:

a. MEDTRONIC fraudulently concealed and misrepresented the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the off-label use of Infuse®;

b. MEDTRONIC fraudulently concealed and misrepresented their practice of promoting and marketing to physicians, including Plaintiff's physicians, the practice of using Infuse® without an LT-Cage™ and placing it via a transforaminal approach;

c. MEDTRONIC fraudulently concealed and misrepresented information about the known comparative risks and benefits of the use of Infuse® and the relative benefits and availability of alternate products, treatments and/or therapies.

309. MEDTRONIC knew, or should have known, that they were concealing and misrepresenting true information about the known comparative risks and benefits of the use of Infuse® and the relative benefits and availability of alternate products, treatments and/or therapies.

310. MEDTRONIC knew that Plaintiff and Plaintiff's physicians would regard the matters Defendants concealed and misrepresented to be important in determining the course of treatment for the Plaintiff, including Plaintiff and Plaintiff's physician's decision whether or not to use Infuse® without an LT-Cage™ or to place it via atransforaminal approach in Plaintiff's lumbar spine fusion surgery.

311. MEDTRONIC intended to cause Plaintiff and Plaintiff's physicians to rely on their concealment of information and misrepresentations about the safety risks related to Infuse® to induce them to use of Infuse® off-label for Plaintiff's lumbar spine fusion surgery.

312. Plaintiff and Plaintiff's physicians were justified in relying, and did rely, on MEDTRONIC's concealment of information and misrepresentations about the safety risks related to Infuse® in deciding to use Infuse® in an off-label manner for Plaintiff's lumbar spine fusion surgery.

313. As the direct, proximate, and legal cause and result of the Defendants' fraudulent concealment and misrepresentations and suppression of material health and safety risks relating to Infuse® and Defendants' dangerous and irresponsible marketing and promotion practices, Plaintiff has been injured and has incurred damages, including but not limited to, medical and hospital expenses, lost wages and lost earning capacity, physical and mental pain and suffering, and loss of the enjoyment of life.

314. Plaintiff ROBERT SKOUBO has been injured and suffers injuries to his body and mind, the exact nature of which is not completely known to date.

315. Plaintiff ROBERT SKOUBO has sustained economic losses, including loss of earnings and diminution of his earning capacity, the exact amount of which is presently unknown.

316. Plaintiff ROBERT SKOUBO will be required to incur additional medical expenses in the future as a result of the injury and damages he has suffered.

317. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

318. Defendants' conduct as alleged above was malicious, intentional, and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiff and as such, warrants an imposition of punitive damages.

SECOND CAUSE OF ACTION
Strict Products Liability- Failure to Warn

319. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

320. MEDTRONIC had a duty to warn Plaintiff and Plaintiff's physicians about the dangers of Infuse® of which it knew, or in the exercise of ordinary care, should have known, at the time the Infuse® left MEDTRONIC's custody or control.

321. MEDTRONIC did know of these dangers of off-label use of Infuse®, and breached this duty by failing to warn Plaintiff and Plaintiff's physicians of the dangers of its off-label practice of using Infuse® without an LT-Cage™ and placing it via a transforaminal approach in a lumbar spine fusion surgery.

322. Defendants, and each of them, knew that Infuse® would be purchased and used without inspection for defects in the design of the product.

323. The Infuse® used in Plaintiff was defective when it left the control of each of these Defendants.

324. Defendants knew or should have known of the substantial dangers involved in the reasonably foreseeable use of Infuse®, whose defective design, manufacturing, and lack of sufficient warnings caused Infuse® to have an unreasonably dangerous propensity to cause catastrophic injuries.

325. The warnings accompanying the Infuse® product did not adequately warn Plaintiff and Plaintiff's physicians, in light of Defendants' scientific and medical knowledge at the time, of the dangers associated with Infuse® when used without an LT-Cage™ and when placed via a transforaminal approach in a lumbar spine fusion surgery including, but not limited to, pain and weakness in the limbs, radiculitis, ectopic bone formation, osteolysis, and worse global outcomes than alternative, currently available treatments.

326. The warnings accompanying the Infuse® product failed to provide the level of information that an ordinary physician or consumer would expect when using the product in a manner reasonably foreseeable to the MEDTRONIC Defendants. The MEDTRONIC Defendants either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to the off-label use of Infuse®, including but not limited to the risk of ectopic or uncontrolled bone growth.

327. MEDTRONIC failed to provide adequate warnings, instructions, guidelines, or admonitions to members of the consuming public, including Plaintiff and Plaintiff's physicians, of the problems with the off-label use of Infuse® which Defendants knew, or in the

exercise of reasonable care should have known, to have existed with the off-label use of Infuse®.

328. Defendants knew that these substantial dangers are not readily recognizable to an ordinary consumer or physician and that consumers and physicians would purchase Infuse® without inspection.

329. At the time of Plaintiff's injury, Infuse® was being used in a manner promoted by Defendants and in a manner that was reasonably foreseeable by Defendants as involving substantial danger that was not readily apparent to its users.

330. Plaintiff's physician relied on the MEDTRONIC Defendants' inadequate warnings in deciding to use Infuse® in an off-label manner. Plaintiff and Plaintiff's physician would not have used Infuse® off-label without an LT-Cage™ and by placing via a transforaminal approach, had they known of the true safety risks related to Infuse®.

331. As a direct and proximate result of one or more of the above-listed dangerous conditions and defects, and of MEDTRONIC's failure to provide adequate warnings about them, Plaintiff sustained serious injuries of a personal and pecuniary nature from approximately July 21, 2010 to the present.

332. Plaintiff ROBERT SKOUBO has been injured and suffers injuries to his body and mind, the exact nature of which is not completely known to date.

333. Plaintiff ROBERT SKOUBO has sustained economic losses, including loss of earnings and diminution of his earning capacity, the exact amount of which is presently unknown.

334. Plaintiff ROBERT SKOUBO will be required to incur additional medical expenses in the future as a result of the injury and damages he has suffered.

335. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

336. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiff and as such, warrants an imposition of punitive damages.

THIRD CAUSE OF ACTION
Strict Products Liability- Design Defect

337. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

338. Defendants' Infuse® device was defectively designed at the time that it left the Defendants' control and was placed into the stream of commerce. The device reached Plaintiff without a substantial change in the condition in which it was sold.

339. Defendants' Infuse® device was defectively designed because the design was unsafe when used in the manner promoted by Defendants and/or in a manner reasonably foreseeable by Defendants. The Infuse® product failed to perform as safely as an ordinary consumer would expect when used, as it was promoted by the MEDTRONIC Defendants for use off-label without an LT-Cage™ and placement via a transforaminal approach in lumbar spine fusion surgeries.

340. Defendants' Infuse® device was defectively designed because the risks of danger in the design outweigh the benefits of the design.

341. The Infuse® product was designed in a way that caused users to suffer injuries including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone growth, osteolysis, and poorer global outcomes than equally effective, alternate designs and treatments.

342. The foreseeable risks of harm posed by using the Infuse® product in a manner promoted by Defendants could have been reduced or avoided by adopting a reasonably alternative design. Defendants did not adopt a design that would have rendered the Infuse® product reasonably safe.

343. Plaintiff and Plaintiff's physicians used Infuse® in a manner intended and reasonably foreseeable by Defendants.

344. Plaintiff was not aware of the aforementioned defects at any time prior to the injuries caused by the Infuse®.

345. As a legal and proximate cause of the aforementioned defects of Infuse®, Plaintiff has sustained the injuries and damages set forth herein.

346. Plaintiff ROBERT SKOUBO has been injured and suffers injuries to his body and mind, the exact nature of which is not completely known to date.

347. Plaintiff ROBERT SKOUBO has sustained economic losses, including loss of earnings and diminution of his earning capacity, the exact amount of which is presently unknown.

348. Plaintiff ROBERT SKOUBO will be required to incur additional medical expenses in the future as a result of the injury and damages he has suffered.

349. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

350. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiff and as such, warrants an imposition of punitive damages.

FOURTH CAUSE OF ACTION
Strict Products Liability- Misrepresentation

351. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

352. Specific defects in the Infuse® product, as specified above in this Complaint, rendered it defective and unreasonably dangerous.

353. At all relevant times, Defendants were engaged in the business of selling Infuse® for resale or use, and in fact did sell the Infuse® device used by Plaintiff's implanting surgeon. In the course of marketing Infuse , Defendants made untrue representations of material facts and omitted material information to Plaintiff, Plaintiff's physicians, and the public at large. Defendants sponsored biased medical trials, reports, and articles that wrongfully and inaccurately claimed that the dangers inherent to off-label use of Infuse® did not exist or were significantly less than the actual dangers. Defendants made these representations and omissions to guide doctors and physicians in their purchase and use of Infuse®.

354. Plaintiff and Plaintiff's physicians would not have purchased and made off-label use of Infuse® without an LT-Cage™ and placed Infuse® via a transforaminal approach for a lumbar spine fusion surgery, had they known of the true safety risks related to Infuse®.

355. Defendants were negligent in making the untrue misrepresentations and omitting material information because Defendants knew, or had reason to know, of the actual, unreasonable dangers and defects in their Infuse® product.

356. Plaintiff and Plaintiffs' physicians would reasonably be expected to use Infuse®. Defendants intended to induce Plaintiff and Plaintiff's physicians to rely on their misrepresentations and omissions to use Infuse® in an off-label manner.

357. Plaintiff and Plaintiff's physicians were justified in relying, and did rely, on the misrepresentations and omissions about the safety risks related to Infuse® in deciding to use

Infuse® off-label without an LT-Cage™ and via a transforaminal approach for a lumbar spine fusion surgery.

358. As the direct, producing, proximate and legal result of the Defendants' misrepresentations, Plaintiff has suffered severe physical pain, medical and hospital expenses, lost wages, pain and suffering, and pecuniary loss.

359. Plaintiff ROBERT SKOUBO has been injured and suffers injuries to his body and mind, the exact nature of which is not completely known to date.

360. Plaintiff ROBERT SKOUBO has sustained economic losses, including loss of earnings and diminution of his earning capacity, the exact amount of which is presently unknown.

361. Plaintiff ROBERT SKOUBO will be required to incur additional medical expenses in the future as a result of the injury and damages he has suffered.

362. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

363. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiff and as such, warrants an imposition of punitive damages.

FIFTH CAUSE OF ACTION
Product Liability- Negligence

364. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

365. MEDTRONIC marketed their Infuse® product to and for the benefit of Plaintiff, and additionally marketed it to Plaintiff's physicians, and these Defendants knew or should have known that Plaintiff and Plaintiff's physicians would use their product, including for the off-

label use of Infuse® without an LT-Cage™ and via a transforaminal approach in a lumbar spine fusion.

366. Defendants owed Plaintiff and Plaintiff's physicians duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge.

367. Defendants had a confidential and special relationship with Plaintiff due to (a) Defendants' vastly superior knowledge of the health and safety risks relating to Infuse®, and (b) Defendants' sole and/or superior knowledge of their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse® without an LT-Cage™ and via a transforaminal approach in lumbar spine surgeries.

368. As a result, Defendants had an affirmative duty to fully and adequately warn Plaintiff and Plaintiff's physicians of the true health and safety risks related to the off-label use of Infuse®, and Defendants had a duty to disclose their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse® without an LT-Cage™ and via a transforaminal approach for lumbar spine surgeries. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of the off-label use of Infuse® to Plaintiff and Plaintiff's physicians.

369. Misrepresentations made by Defendants about the health and safety of Infuse® independently imposed a duty upon Defendants to fully and accurately disclose to Plaintiff and Plaintiff's physicians the true health and safety risks related to Infuse® and a duty to disclose their dangerous and irresponsible off-label promotion and marketing practices.

370. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Defendants breached their duties to Plaintiff and to Plaintiff's physicians.

371. The following sub-paragraphs summarize, inter alia, Defendants' breaches of duties to Plaintiff and Plaintiff's physicians and describe categories of acts or omissions constituting breaches of duty by these Defendants. Each and/or any of these acts or omissions establishes an independent basis for these Defendants' liability in negligence:

a. Unreasonable and improper promotion and marketing of Infuse® to physicians, including but not limited to, the promotion and marketing of Infuse® for off-label use without an LT-Cage™ in lumbar spine fusion surgeries;

b. Failure to warn physicians and Plaintiff of the dangers associated with Infuse® when used off-label without an LT-Cage™ and via a transforaminal approach in lumbar spine surgery including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes than alternative treatments;

c. Failure to exercise reasonable care by not complying with federal law and regulations applicable to the sale and marketing of Infuse®; and

d. Failure to exercise reasonable care to prevent Infuse® from creating an unreasonable risk of harm to Plaintiff and other consumers who might reasonably be expected to be harmed by Infuse® while it was being used in the manner the MEDTRONIC Defendants should have reasonably expected.

372. Defendants knew, or should have known, that, due to their failure to use reasonable care, Plaintiff and Plaintiff's physicians would use and did use Infuse® to the detriment of Plaintiff's health, safety, and well-being.

373. As the direct, producing, proximate and legal result of the Defendants' misrepresentations, Plaintiff has suffered severe physical pain, medical and hospital expenses, lost wages, pain and suffering, and pecuniary loss.

374. Plaintiff ROBERT SKOUBO has been injured and suffers injuries to his body and mind, the exact nature of which is not completely known to date.

375. Plaintiff ROBERT SKOUBO has sustained economic losses, including loss of earnings and diminution of his earning capacity, the exact amount of which is presently unknown.

376. Plaintiff ROBERT SKOUBO will be required to incur additional medical expenses in the future as a result of the injury and damages he has suffered.

377. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

378. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiff and as such, warrants an imposition of punitive damages.

379. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

SIXTH CAUSE OF ACTION
Breach of Express Warranty

380. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

381. At all times herein mentioned, the MEDTRONIC Defendants utilized journal articles, advertising media, sales representatives/consultants, and paid Key Opinion Leaders to urge the use, purchase, and utilization of the off-label use of Infuse® Bone Graft and expressly warranted to physicians, including Plaintiff's physician and other members of the general public and medical community, that such off-label uses, including uses in lumbar fusion procedures, were safe and effective.

382. Defendants knew or, in the exercise of reasonable diligence, should have known, that the off-label use of Infuse® had the serious side effects set forth earlier and throughout this Complaint.

383. Plaintiff is informed and believes and based thereon alleges that her treating surgeon relied on Defendants' express warranty representations regarding the safety and efficacy of off-label use of Infuse®, but such off-label uses, including uses in lumbar fusion procedures, were not effective, safe, and proper for the use as warranted in that Infuse® was dangerous when put to these promoted uses.

384. Defendants thus breached their express warranty which was a direct and proximate cause of Plaintiff's injuries and damages.

385. Plaintiff ROBERT SKOUBO has been injured and suffers injuries to his body and mind, the exact nature of which is not completely known to date.

386. Plaintiff ROBERT SKOUBO has sustained economic losses, including loss of earnings and diminution of his earning capacity, the exact amount of which is presently unknown.

387. Plaintiff ROBERT SKOUBO will be required to incur additional medical expenses in the future as a result of the injury and damages he has suffered.

388. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

389. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiff and as such, warrants an imposition of punitive damages.

SEVENTH CAUSE OF ACTION
Violation of Oregon's Consumer Protection Statutes

390. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

391. Defendants have a statutory duty to refrain from unfair or deceptive acts or practices in the development, manufacture, promotion and sale of Infuse®.

392. Had the Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for Infuse®, and would not have incurred related medical costs and injuries.

393. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, substantial sums of money from Plaintiff for Infuse® to be implanted off-label that would not have been paid had MEDTRONIC not engaged in unfair and deceptive conduct.

394. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell Infuse® to be used off-label. Each aspect of Defendants' conduct combined to artificially create sales of Infuse®.

395. Defendants are liable to Plaintiff jointly and severally for all general, special and injunctive relief to which Plaintiff is entitled by law. Under statutes enacted in Oregon to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Plaintiff is a consumer who purchased MEDTRONIC's Infuse® product pursuant to a consumer transaction for personal use and is therefore subject to protection under such legislation.

396. Under statutes enacted in Oregon to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, MEDTRONIC is the

supplier, manufacturer, advertiser, and seller, who is subject to liability under such legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

397. Defendants violated the statutes enacted in Oregon to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that Infuse® was fit to be used for the purpose for which it was advertised, when in fact Infuse® was defective and dangerous when used off-label, and by other acts alleged herein. These representations were made in uniform promotional materials, at medical conferences, and in journal articles written collaboratively by MEDTRONIC and Key Opinion Leaders.

398. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under the statutes enacted in Oregon to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

399. Defendants had actual knowledge of the dangerous adverse events associated with the off-label use of Infuse®, and failed to take any action to cure such defective and dangerous conditions or to advertise Infuse® exclusively for safe and approved purposes.

400. Plaintiff and the medical community relied upon Defendants' misrepresentations and omissions in determining which bone graft product to utilize.

401. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and practices in violation of the Oregon Unlawful Trade Practices Act, O.R.S. § 646.605, et seq.

402. As the direct, producing, proximate, and legal result of the Defendants' violations of the Oregon Unlawful Trade Practices Act, O.R.S. § 646.605, et seq., and the parallel duties arising

under federal law as articulated in this Complaint, Plaintiff has suffered injuries and incurred damages.

403. Plaintiff ROBERT SKOUBO has been injured and suffers injuries to his body and mind, the exact nature of which is not completely known to date.

404. Plaintiff ROBERT SKOUBO has sustained economic losses, including loss of earnings and diminution of his earning capacity, the exact amount of which is presently unknown.

405. Plaintiff ROBERT SKOUBO will be required to incur additional medical expenses in the future as a result of the injury and damages he has suffered.

406. Plaintiff is therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

407. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiff and as such, warrants an imposition of punitive damages.

EIGHTH CAUSE OF ACTION
Loss of Consortium

408. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

409. At all relevant times, Plaintiff DIANE SKOUBO, was the lawful spouse of Plaintiff ROBERT SKOUBO, and as a direct and proximate result of negligence, actions, representations, and omissions as set forth above, Plaintiff, DIANE SKOUBO, has suffered the loss of her husband's support and services, companionship, protection, consortium, and the care and comfort of his society. These losses are either permanent to continuing in nature, and DIANE SKOUBO will suffer these losses in the future.

ADDITIONAL ALLEGATIONS REGARDING CLAIM FOR PUNITIVE DAMAGES

410. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further alleges as follows:

411. At all times herein referenced, officers, directors, and managing agents of MEDTRONIC knew, were aware, and concealed, hid, and/or otherwise downplayed the true risks of non-FDA-approved off-label uses of its Infuse® Bone Graft product.

412. At all times herein referenced, officers, directors, and managing agents of MEDTRONIC knew and were aware that numerous people suffered from ectopic bone formation, radiculitis, osteolysis, cage migration, and worse overall outcomes as a result of non-FDA-approved, off-label uses of its Infuse® Bone Graft product.

413. MEDTRONIC designed, engineered, developed, manufactured, fabricated, assembled, equipped, tested or failed to test, inspected or failed to inspect, labeled, advertised, promoted, marketed, supplied, distributed, wholesaled, and sold Infuse®, a product which Defendants knew to be dangerous and unsafe for the purpose for which it was intended to be used, namely, as a bioengineering bone graft device in spinal fusion surgeries.

414. At all times herein mentioned, prior to and at the time that Defendants designed, engineered, developed, manufactured, fabricated, assembled, or failed to test, promoted, marketed, supplied, distributed, and/or sold Infuse® to Plaintiff and Plaintiff's physicians, and prior to the time that said product was used, MEDTRONIC knew, or should have known, that Infuse® was defectively designed and manufactured, that it had extremely dangerous propensities and defects, and that it had defects which would cause serious injuries and damage to users of said product, thereby threatening the life and health of the users. Further, at all

times, all Defendants knew that Infuse® had caused serious injuries and damage to other members of the public.

415. At all times herein mentioned, MEDTRONIC, despite the actual knowledge described hereinabove, intentionally suppressed the complaints and adverse events, actively concealed and downplayed the risks associated with Infuse®, actively promoted the off-label use of Infuse®, failed to warn Plaintiff, Plaintiff's physician, and the medical community of the true risks associated with Infuse®, and saturated the scientific and medical literature with biased, industry-funded studies to conceal the true risks of Infuse®, and otherwise failed to warn Plaintiff and the medical community of the true risks of off-label use of Infuse®.

416. At all times herein mentioned, MEDTRONIC had actual knowledge of the facts hereinabove alleged demonstrating that serious injuries occur to patients in which Infuse® was implanted, particularly in an off-label manner such as the transforaminal approach fusion surgery Plaintiff underwent. Nevertheless, MEDTRONIC deliberately suppressed, concealed, downplayed, and/or otherwise hid any information demonstrating the true risks associated with Infuse® from Plaintiff, the medical community, and/or the general public. MEDTRONIC continued to actively promote the off-label use of Infuse® to spine surgeons in an effort to maintain and increase Infuse®'s enormous profitability.

417. As a legal and proximate result of MEDTRONIC's misconduct, callous disregard, and omissions, as herein alleged, Plaintiff sustained the injuries, damages, and losses set forth above.

418. MEDTRONIC's conduct and omissions, as set forth above, in allowing such an extremely dangerous product to be used by members of the general public, including Plaintiff, constitutes fraud, malice, and oppression toward Plaintiff and others.

419. Plaintiff is therefore entitled to exemplary or punitive damages, which would serve to punish the Defendants and to deter wrongful conduct in the future.

420. Plaintiff is therefore entitled to judgment against Defendants as hereinafter set forth.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests of this Court the following relief:

A. For general damages, in an amount to be proven at the time of trial;

B. For medical, incidental, hospital, psychological care and other expenses, in an amount to be proven at the time of trial;

C. For loss of earnings and earning capacity, in an amount to be proven at the time of trial;

D. For an award of pre-judgment and post-judgment interest as provided by law;

E. For consequential damages, in an amount to be proven at the time of trial;

F. For exemplary or punitive damages against Defendants MEDTRONIC, INC. and MEDTRONIC SOFAMOR DANEK USA, INC., as provided by law;

G. For an award providing for payment of costs of suit and attorneys' fees; and;

H. For such other and further relief as this Court may deem just and proper.

Dated: March 21, 2014

/s/ Jeffrey A. Bowersox

Jeffrey A. Bowersox
Bowersox Law Firm, P.C.
One Kruse Woods Meadows
5285 Meadows Road
Suite 320
Lake Oswego, OR 97035
503.452.5858 Voice
Jeffrey@BowersoxLaw.com

GOLDENBERGLAW, PLLC
Stuart L. Goldenberg *(pro hac vice pending)*
Marlene J. Goldenberg *(pro hac vice pending)*
800 LaSalle Avenue, Suite 2150
Minneapolis, MN 55402
slgoldenberg@goldenberglaw.com
mjgoldenberg@goldenberglaw.com
Tel: (612) 333-4662
Fax: (612) 367-8107

BRANCH LAW FIRM
Turner W. Branch *(pro hac vice pending)*
Margaret M. Branch *(pro hac vice pending)*
Adam T. Funk *(pro hac vice pending)*
2025 Rio Grande Boulevard NW
Albuquerque, NM 87104
tbranch@branchlawfirm.com
mbranch@branchlawfirm.com
afunk@branchlawfirm.com
Tel: (505) 243-3500
Fax: (505) 243-3534

Attorneys for Plaintiffs
ROBERT SKOUBO and DIANE SKOUBO